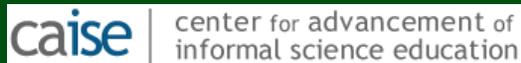


# Ethical and practical solutions for evaluation studies: Protecting human subjects

Josh Gutwill

Acting Director of Visitor Research

July 26, 2008



# Overview

- Why this workshop?
- Ethical concerns - examples of two studies
- Government response - “Common Rule”
- Responding effectively to regulations
  - Defining research
  - Writing protocols
  - Finding and working with IRBs
  - Working with NSF Program officers

# Impetus for this workshop

- System for protecting HS for ~30 years
- Applied to research, not evaluation
- Now line is blurring
  - Evaluators using new methods (audio/video)
  - More comparative studies -> more generalizable
- Learn about the system, when it applies, and how to use it effectively



# Ethical Concerns

- Why worry about studies with humans?
- Recent medical and psychological research
  - Tuskegee experiment (1932-1972)
  - Milgram Experiment (1961)



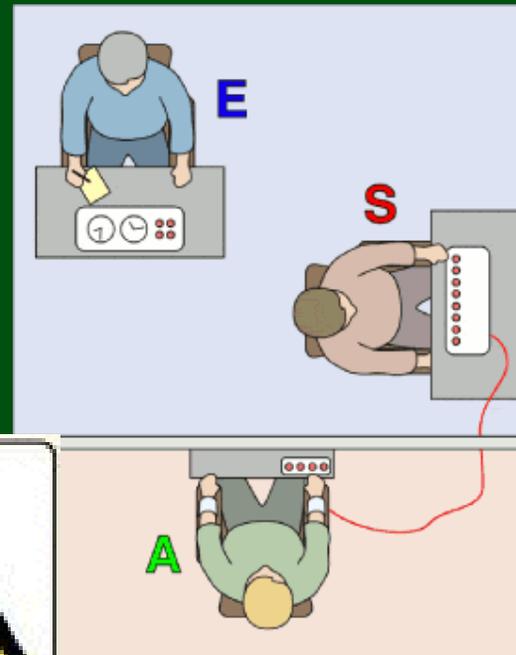
# Tuskegee Experiment

Between 1932 and 1972, the U.S. Public Health Service (PHS) conducted an experiment on 399 black men in the late stages of syphilis to observe the natural progression of the disease if left untreated. These men, for the most part illiterate sharecroppers from one of the poorest counties in Alabama, were never told what disease they were suffering from or of its seriousness. Informed that they were being treated for “bad blood,” they were offered free medical treatment, rides to the clinic, meals and burial insurance in case of death in return for participating. By 1947 penicillin had become the standard treatment for syphilis. The Tuskegee scientists withheld penicillin and information about penicillin, purely to continue to study how the disease spreads and kills. Participants were also prevented from accessing syphilis treatment programs that were available to other people in the area.

<http://www.infoplease.com/ipa/A0762136.html>

[http://en.wikipedia.org/wiki/Tuskegee\\_experiment](http://en.wikipedia.org/wiki/Tuskegee_experiment)

# Milgram Obedience Study (1961)



# Belmont Commission (1974-9)

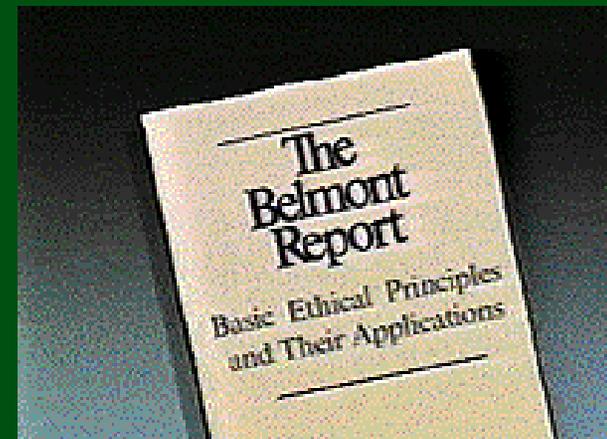


# Belmont Commission (1974-9)

## Three basic principles for HS research

### – Respect for Persons

- Protect autonomy (reduce coercion; extra protection for people w/ diminished autonomy)
- Treat with respect & courtesy
- Informed consent



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### – Justice

- Fairness in distribution of benefits and costs

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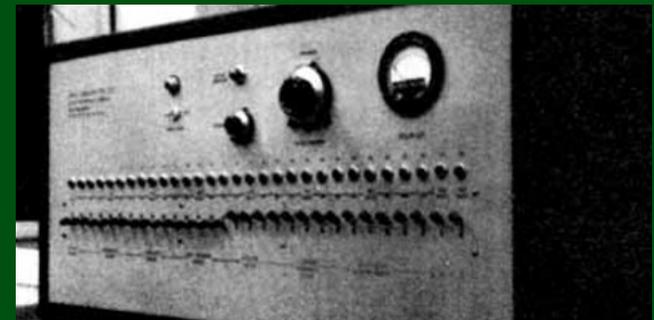
## The New York Times

### 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

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



# Applying principles

Respect (informed consent, autonomy, protection)

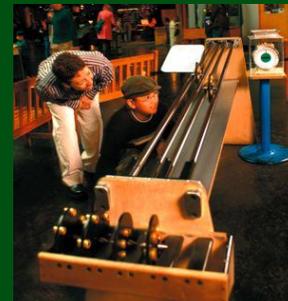
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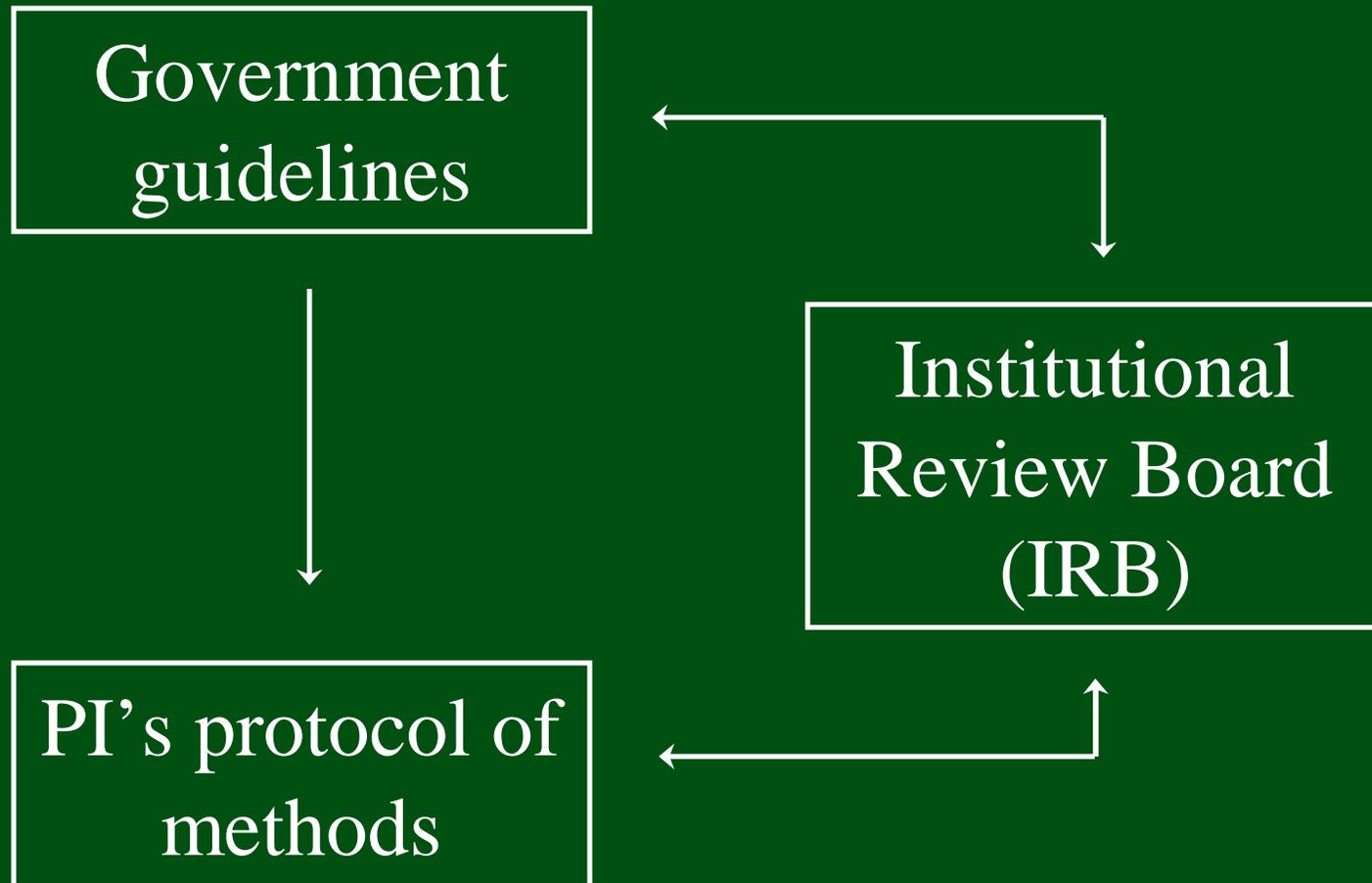
Where did Tuskegee and Milgram go awry?

What might be the risks in informal environments?

- Interviewing people
- Recording people



# System for protecting subjects



# How do we deal with this?

- Learn the guidelines
  - Protecting human subjects
    - Apply Belmont principles
  - Defining research
  - Defining “exempt” research
- Write research/evaluation protocols
- Work w/ Institutional Review Board (IRB)
- Work w/ NSF program officers

# Defining “Research”

- Definition of Human Subjects Research
  - **Systematic** investigation **designed** to contribute to **generalizable** knowledge
  - Obtaining **identifiable** private information about living individuals
  - Involves **intervention** or **interaction** with individuals
- Line is blurring between “research” and “evaluation”

# What is “exempt”?

- Research in established educational settings
  - Comparing diff curricula, or teaching techniques
- Tests, surveys or observations of public behavior, as long as:
  - no identifiable information is obtained
  - it doesn't involve prisoners or children\*
  - there is no risk of harm to the subject's reputation
- Data already exists in public domain or if identity is unknown to researcher
- Other types of studies
  - Certain Research projects by government
  - Taste and food quality tests

# Case studies

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  - Defining research
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  - What do you want to find out?
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- Design your study
  - What do you want to find out?
  - How can you do it while minimizing risks?
- Get resources from an IRB
  - See packet for UCB's guidelines
  - Ask your IRB for guidelines
- Ask for colleagues' protocols
  - Email me

# Working with IRBs

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    - Portland State University
- All boards interpret guidelines differently
- Try to establish relationship with person at IRB

# Working with NSF

- Methods determine if IRB oversight needed

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- Methods determine if IRB oversight needed
- At time of proposal submission/negotiation:
  - Some need IRB approval
  - Some need PI assurance that IRB will be used
  - Some need nothing