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Histories, Scandals and Tragedies:
*Beecher, Tuskegee, Willowbrook
and the Rest*

October 17, 2018



History

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What This Module Covers:

Before discussing the current system for the protection of human subjects in research, it is important to review some of the significant historical events that have influenced current ethical guidelines and HHS regulations.

This module covers the following topics:

- Goals and Principles of Human Subjects Protection
- Nazi Medical War Crimes
- Syphilis Study at Tuskegee
- Timeline of Important Historical Events

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Historical Events

The Nuremburg Code

In the August 1947 verdict, the judges included a section called **Permissible Medical Experiments**. This section became known as the [Nuremburg Code](#) and was the first international code of research ethics.

This set of directives established the basic principles that must be observed in order to satisfy moral, ethical, and legal concepts in the conduct of human subject research. The Code has been the model for many professional and governmental codes since the 1950s and has, in effect, served as the first international standard for the conduct of research.

▶ [The Code Provides Ten Directives for Human Experimentation](#)



View from above of the defendants dock during a session of the Medical Case (Doctors) Trial in Nuremberg, which ran from December 9, 1946 to July 19, 1947.

Photo source: Photo Archive, United States Holocaust Memorial Museum, courtesy of Hedwig Wachenheimer Epstein; used with permission.



Dr. Leo Alexander, Boston neurologist and psychiatrist who served as consultant to the Secretary of War and to the Chief of Counsel for War Crimes at the trial, examines a Polish girl who was permanently crippled by physician experiments. (World Wide Photo)



Karl Brandt, personal physician to Adolph Hitler and Reich Commissioner for Health and Sanitation, sentenced to death by hanging. (U.S. Army Photo, Ray D'Addario)

Andrew Ivy



The Nuremberg Code, 1947

The voluntary consent of the human subject is absolutely essential.

“It was a good ethics code for barbarians.”

Jay Katz (1922-2008) on his medical school professors' reaction.

Thalidomide



The “Banality of Evil”

- The Eichmann Trial, Jerusalem, 1961



- Hannah Arendt, The New School



Stanley Milgram's Obedience to Authority Experiment



Public Announcement

WE WILL PAY YOU \$400 FOR ONE HOUR OF YOUR TIME

Persons Needed for a Study of Memory

This will pay you \$400 for one hour of your time in the laboratory. You will be paid \$100 for the first 15 minutes, \$150 for the next 30 minutes, and \$150 for the last 15 minutes. You will be paid \$400 for the entire hour. You will be paid \$400 for the entire hour. You will be paid \$400 for the entire hour.

This study is being conducted in the laboratory of the Department of Psychology, Harvard University. It is a study of memory. It is a study of memory. It is a study of memory.

Basic salary	\$100.00	Experimental fee
Pay for materials	\$150.00	Transportation
Travel	\$150.00	Meals and refreshments
Other	\$100.00	Taxes

It is expected that you will be paid \$400 for the entire hour. It is expected that you will be paid \$400 for the entire hour. It is expected that you will be paid \$400 for the entire hour.

If you have any questions, please call the laboratory at 617-495-6200. If you have any questions, please call the laboratory at 617-495-6200. If you have any questions, please call the laboratory at 617-495-6200.

There will be a \$100 fee for the first 15 minutes of your time. There will be a \$100 fee for the first 15 minutes of your time. There will be a \$100 fee for the first 15 minutes of your time.

NAME (Please Print) _____

ADDRESS _____

TELEPHONE NO. _____ (Area Code) _____

AGE _____ GRADE _____ SEX _____

CITY/TOWN _____

EDUCATION _____ EXPERIENCE _____ OCCUPATION _____

Henry Beecher

Harvard professor of anesthesiology

NEJM paper, 1966,

“Ethics and Clinical Research”

Describes 22 cases of unethical human experiments in the published literature, e.g.,

- Brooklyn Jewish Chronic Disease Hospital
- Willowbrook State Hospital

Rejected “rigid rules” in favor of the “virtuous investigator”



Jewish Chronic Disease Hospital Case, 1963

- Live cancer cells injected into 22 debilitated patients
- Intended to measure patients' ability to reject foreign cells
- No informed consent
- State of New York brought charges against Dr. Chester Southam and Dr. Emanuel Mandel
- Suspended medical licensure for one year

Saul Krugman and Willowbrook

- “...were bound to be exposed...”
- Special unit isolated from other infections
- Likely to have subclinical infection and immunity
- Parents gave informed consent
 - Krugman, *The Lancet* 1971



Beecher's LSD Papers

Lasagna L, von Felsinger JM, Beecher HK. Drug-induced mood changes in man. 1. Observations on healthy subjects, chronically ill patients, and "postaddicts." J Am Med Assoc 1955; 157:1006-1020.

von Felsinger JM, Lasagna L, Beecher HK. Drug-induced mood changes in man. 2. Personality and reactions to drugs. J Am Med Assoc 1955; 157:1113-1119.

von Felsinger JA, Lasagna L, Beecher HK. The response of normal men to lysergic acid derivatives (di- and mono-ethyl amides). J Clin Exp Psychopathol 1956; 17:414-428.*

*DoD funded; "The drugs were administered as unknowns"
subjects appear to have been college students.

file 15

June 15, 1950

Colonel William S. Stone
Department of the Army
Washington 25, D.C.

Dear Colonel Stone:

I have not been forgetful of the study you mentioned to me at the meeting of the Committee on Surgery at the National Research Council on May 29, concerning an examination of agents that might be used in narcoanalysis or for use as "truth sera." I have been deliberate about this matter because I wanted to be very sure I got the best possible advice, as far as the psychiatric side of the study goes. Stanley Cobb, who is Professor here at Harvard, as you know, and also Chief of the Psychiatric Department at the Massachusetts General Hospital, is a very wise counselor. He thinks this problem is one of importance and one which ought to be looked into. I have found an able young psychiatrist, very closely associated with Dr. Cobb, who, I believe, may be interested in participating in such a study, if it is undertaken here.

It seems to me that the method of attack would have to be designed not only to see which of the many available agents might facilitate probing of the subconscious, but also which agents might make it possible to get at deliberately suppressed information. I assume that the Army would be at least as interested in this latter problem as in the former. It seems to me, too, that two groups of subjects would need to be studied, the catatonics probably, and healthy young volunteers. There is, as I know you will realize as well as I, a considerable problem here in the use of healthy young volunteers. I have been trying to get the best advice possible as to whether any damage might be done to such individuals by a study of this kind. Wise advisers believe not. It might be possible also to get the cooperation of some of the life-teners at the Charlestown State Prison nearby; however, I approach that group with considerable reluctance. Agents to be studied fall into many classes. As you probably know, a number of synthetic agents in the mescoline group are being developed. (The Russians are said to be using mescoline.) As a matter of fact, one of my good friends, an organic chemist, is active in the synthesis of these agents.

I believe we have an almost ideal set-up here in Boston for study of this problem: here at the Massachusetts General Hospital, at our own McLean Sanitarium, and at the Boston Psychopathic Hospital (I have not discussed the matter with the authorities of this latter place as yet).

I simply send you these notes to let you know that I am working on the problem. I do not believe it will be possible to have even a tentative proposal ready for you before the middle of July. Unless there is some reason for particular haste, I shall set that as a tentative deadline for getting a proposal in to you.

Very sincerely,

Henry K. Beecher, M.D.

HKB:rs

Dan Callahan was a subject in a Beecher study of “speed”, 1960

“Then, around 1971 or so I read Beecher's CV since he was part of our [the Hastings Center's] project on brain death. I noticed in his list of publications a project he had run on amphetamines that had involved swimmers and runners in the early 1960s--and that's how I first learned what the research was and who had run it! “

-Dan Callahan to JDM, 11/25/14





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Henry Knowles Beecher Award



The Center's Henry Knowles Beecher Award recognizes individuals who have made a lifetime contribution to ethics and the life sciences and whose careers have been devoted to excellence in scholarship, research, and ethical inquiry. Recipients are nominated by a committee of The Hastings Center's Fellows, an elected group of eminent scholars, and approved by the Board of Directors. The award is named after the first recipient, the late Henry Knowles Beecher, MD, a distinguished physician in the field of anesthesiology who, in the 1960's, courageously shed light on ethically questionable practices in human subjects research. By those actions, Dr. Beecher helped give birth to the field of bioethics and became one of its pioneers.

Beecher on Informed Consent

- 1962 Harvard protest to DoD re the Nuremberg Code
- Informed consent requirement would “cripple” US research (Beecher to Kefauver, 1962)*
- Worries about impact of 1960s LSD use (see Moreno, “Acid Brothers”)

*Thanks to David Podolsky

Enlarged Edition

Including a Retrospect on Ethical Issues

Tearoom Trade

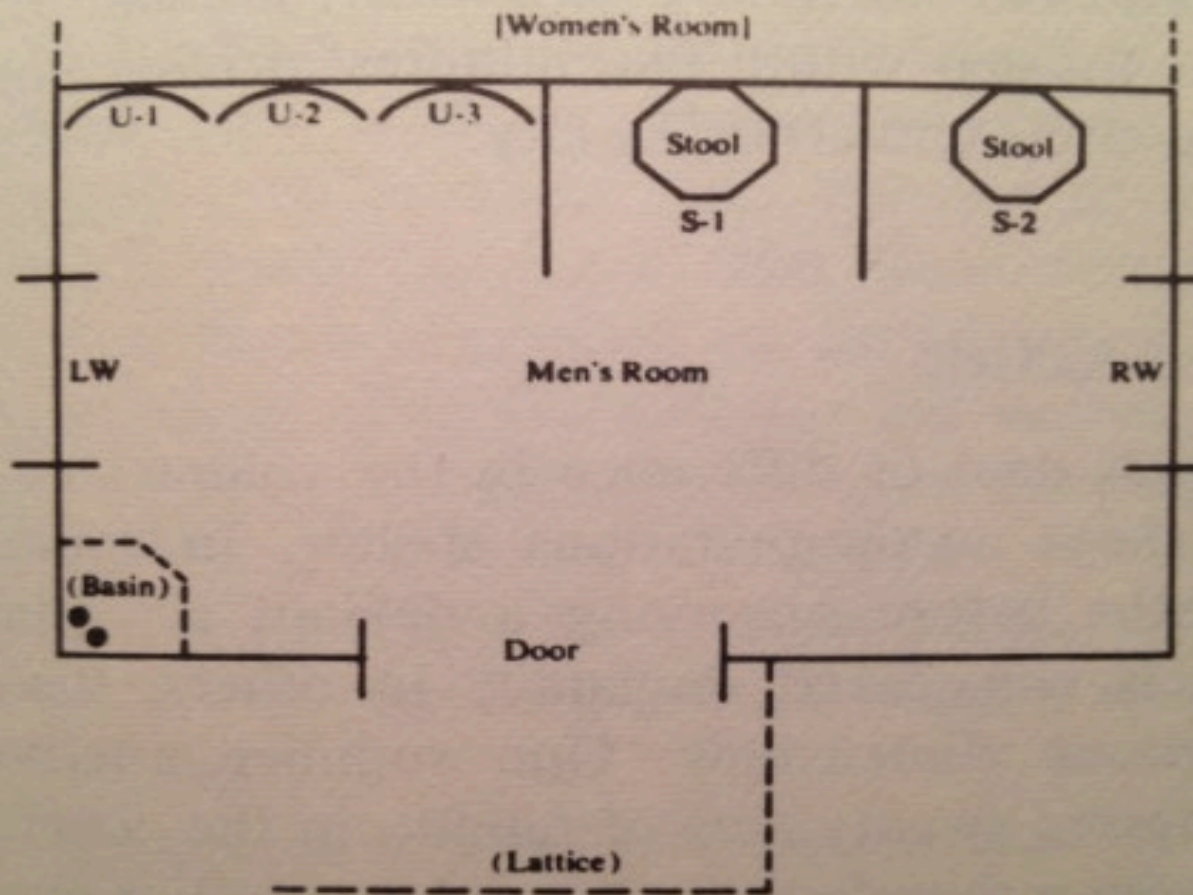
Impersonal
sex
in public
places

Laud
Humphreys

Recipient of the C. Wright Mills Award
With a foreword by Lee Rainwater



Figure 1.1
Diagram of Typical Public Park Restroom



KEY:

U-1, U-2, U-3 = Urinals

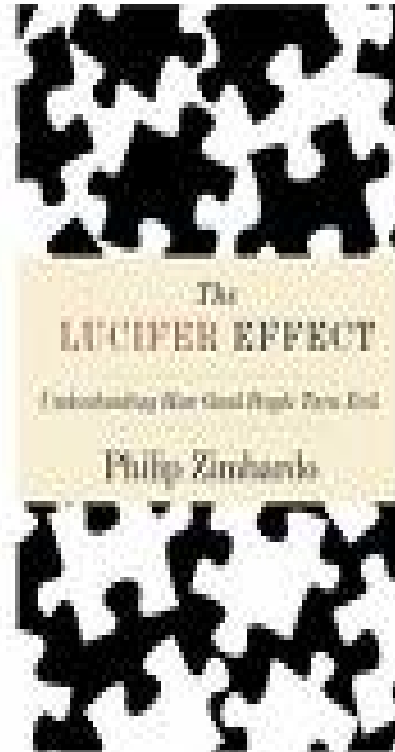
S-1, S-2 = Stalls

LW = Left Window

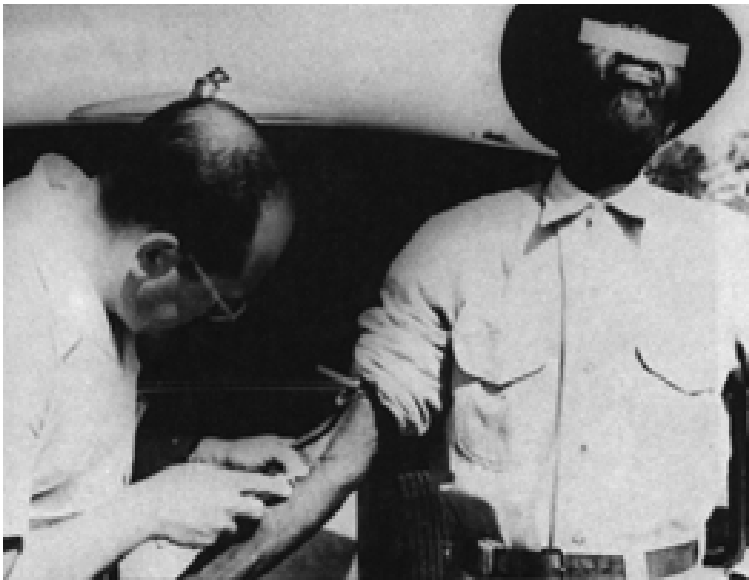
RW = Right Window

┆┆ = Approximately 1 foot

The Stanford Prison Experiment, 1971



USPHS Syphilis Study, 1932-72



(Courtesy National Archives)



The study lasted nearly 40 years
(Courtesy National Archives)

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974-78

- Generally viewed as the first national bioethics commission.
- Established as part of the 1974 National Research Act, the National Commission is best known for the Belmont Report.
- It identified fundamental principles for research involving human volunteers and was the basis of subsequent federal regulation in this area.

THE BELMONT REPORT

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979

- A. Boundaries between research and practice
- B. Ethical principles underlying the conduct of research:
 - Respect for persons
 - Beneficence
 - Justice

RESPECT FOR PERSONS

- Individuals should be treated as autonomous agents (capable of self-determination)
- Persons with diminished autonomy deserve protection
- **Application:** Informed consent

BENEFICENCE

- Do no harm
- Maximize possible benefits and minimize possible harms
- **Application:** Risk/Benefit assessment

JUSTICE

- Fairness in the distribution of the benefits and burdens of research (distributive justice)
- **Application:**
 - Fair procedures and outcomes in the selection of subjects
 - Protection of vulnerable subjects
 - Equitable health care system?

National Commission: Special Protections for “Vulnerable Populations”

- Pregnant women
- Fetuses
- Children
- Prisoners

These special protections have also been written into federal regulation.

But not for those “institutionalized as mentally ill”.

History

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Timeline of Events

Click on the desired date or event to read more about that historical moment in the modern history of human experimentation.

The interface features a vertical timeline on the left with an upward arrow at the top and a downward arrow at the bottom. The years listed are 1991, 1993-1994, 1995, 1996, 1999, 2000, and 2004. The year 2004 is highlighted with a dark grey background. To the right of the timeline is a large orange-bordered panel. At the top of this panel is the title "The Secretary's Advisory Committee on Human Research Protections (2...". Below the title is a faint orange starburst icon. The main text in the panel reads: "The Secretary's Advisory Committee on Human Research Protections (SACHRP) was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects. See www.hhs.gov/ohrp/sachrp."

US apologizes for infecting Guatemalans with STDs in the 1940s

By the CNN Wire Staff

October 1, 2010 10:18 p.m. EDT



President Obama offers "profound apologies" to the Guatemalan president for the tests.

STORY HIGHLIGHTS

- Obama offers "profound apologies"
- Guatemala accepts the apology, the presidential spokesman said
- The United States is launching an investigation
- The research was "reprehensible," the U.S. statement said

Washington (CNN) -- The United States apologized Friday for a 1946-1948 research study in which people in Guatemala were intentionally infected with sexually transmitted diseases.

A statement by Secretary of State Hillary Clinton and Secretary of Health and Human Services Secretary Kathleen Sebelius called the action "reprehensible."

"We deeply regret that it happened, and we apologize to all the individuals who were affected by such abhorrent research practices," the joint statement said. "The conduct exhibited during the study does not represent the values of the United States, or our commitment to human dignity and great respect for the people of Guatemala."

President Barack Obama called his Guatemalan counterpart Friday "offering profound apologies and asking pardon for the deeds of the 1940s," President Alvaro Colom told CNN en Espanol in a telephone interview from Guatemala City.

"Though it happened 64 years ago, it really is a profound violation of human rights," said Colom, who said the report took him by surprise.

Clinton called him on Thursday, he said. "She too offered her apologies," he said, adding that she told him she was ashamed the

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"ETHICALLY IMPOSSIBLE"
STD Research in Guatemala
from 1946 to 1948

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