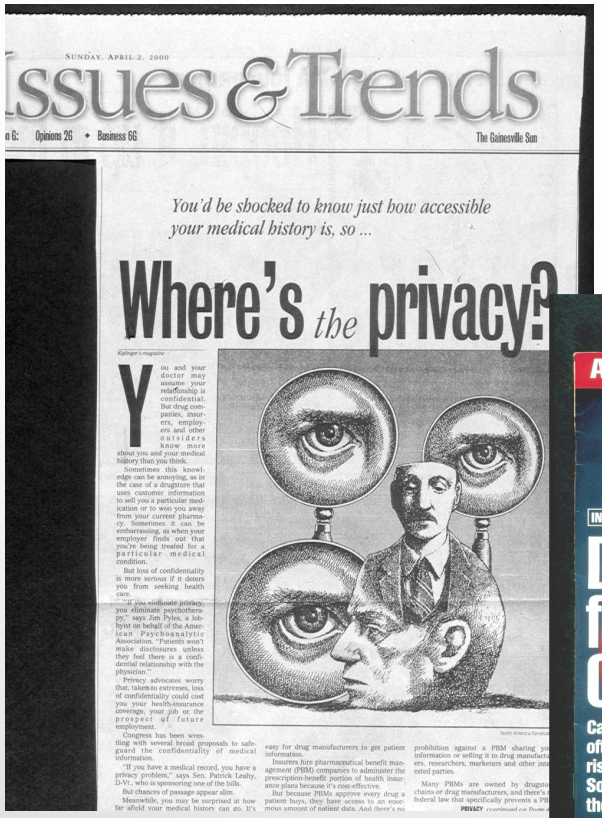
RESEARCH ETHICS: COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)

RACHEL BIBEAULT

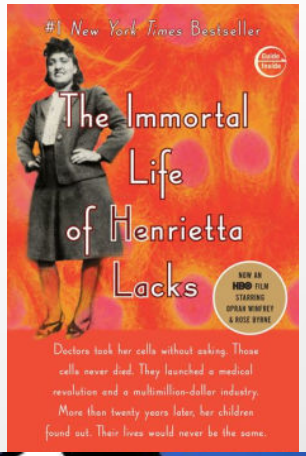
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)

DARTMOUTH COLLEGE



HIPAA

Health Insurance Portability and Accountability Act



GINA

GENETIC INFORMATIO NONDISCRIMINATION ACT

History of ethical abuses and formulation of general ethical principles for research activities

Transformation of ethical principles into U.S. law and international law

Process of ethical review at Dartmouth College

NUREMBERG DOCTORS TRIALS, DECEMBER 1946

"The defendants in this case are charged with murder, tortures and other atrocities committed in the name of medical science."

Brigadier General Telford Taylor: U.S. v. Karl Brandt, et al.

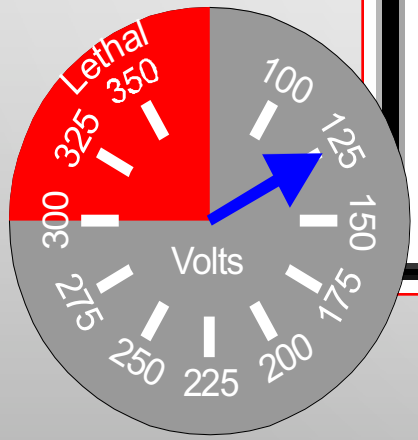
NUREMBERG CODE 1947

- VOLUNTARY INFORMED CONSENT ABSOLUTELY ESSENTIAL
- RESEARCH SHOULD YIELD USEFUL RESULTS
- BASE RESEARCH ON PRIOR WORK
- AVOID PHYSICAL AND MENTAL SUFFERING
- NO EXPECTATION OF DEATH OR DISABLING INJURY
- RISK MUST BE OUTWEIGHED BY IMPORTANCE
- SUBJECTS MUST BE PROTECTED FROM INJURY
- QUALIFIED SCIENTISTS, ADEQUATE FACILITIES
- SUBJECT FREE TO STOP AT ANY TIME
- INVESTIGATOR MUST BE READY TO WITHDRAW SUBJECT.

STAGED EXPERIMENTS ON OBEDIENCE TO AUTHORITY
STANLEY MILGRAM, YALE UNIVERSITY, 1960'S

Fake"Student"

Researcher



Subject - "Teacher"

Milgram Study

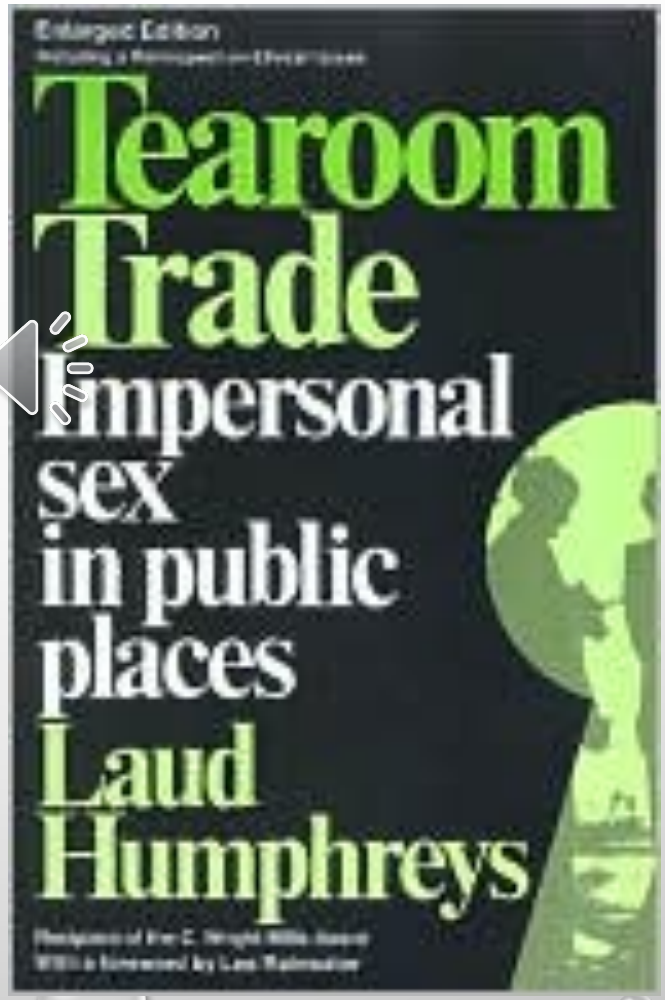
"I observed a mature and initially poised businessman enter the laboratory smiling and confident. Within twenty minutes he was reduced to a twitching, stuttering wreck,who was rapidly approaching a point of nervous collapse... And yet he continued to respond to every word of the experimenter, and obeyed to the end."

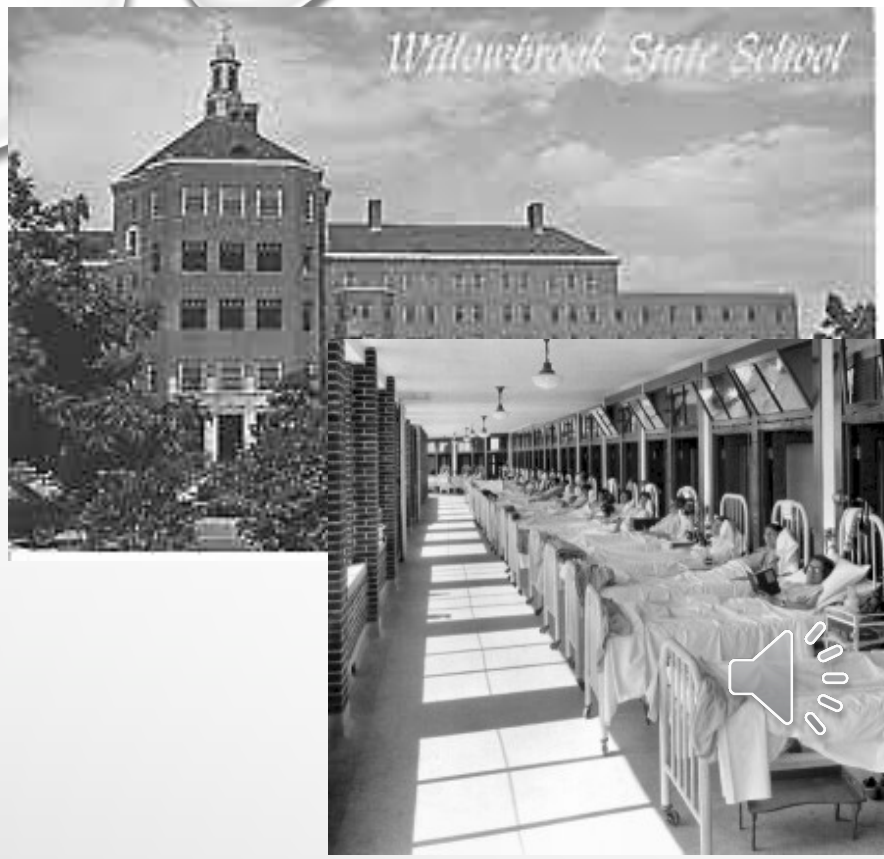
- Stanley Milgram, 1963

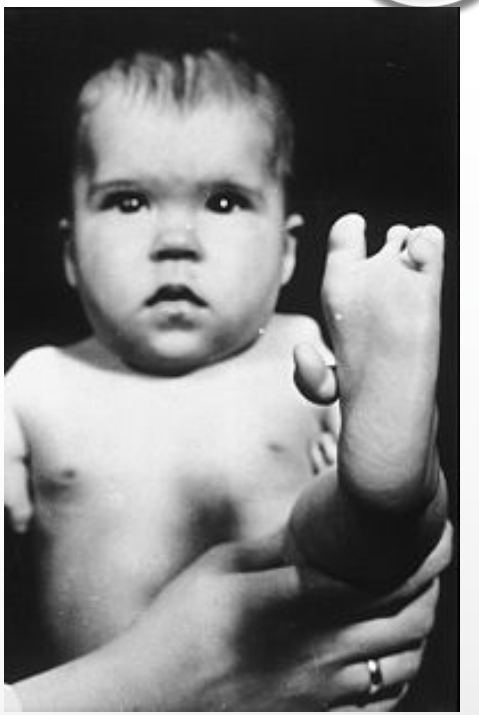
TEAROOM TRADE STUDY

-DECEPTION; INVASION OF PRIVACY

-VULNERABLE POPULATION BECAUSE OF CONTEXT







1950s	Willowbrook hepatitis studies	Deliberate exposure; children
1950s	Jewish Chronic Disease Hospital	Deliberate exposure to cancer cells; debilitated elderly
1950s	Safety of Thalidomide	Teratogenic effects

1932-1972	Tuskegee syphilis study	Deception; deliberate failure to treat; spinal taps; indigent, poorly educated, minority, rural population

Tuskegee Syphilis Study 1932-1972

1974: Congress passes

National Research Act

Growing Concerns…

Special Article: Ethics and Clinical Research
Henry K. Beecher, M.D.
NEJM, 274(24):367-372, June 16, 1966

"…troubling practices"

"…experimentation on a patient not for his benefit, but for that, at least in theory, of patients in general"

CHARGE TO THE NATIONAL COMMISSION

- IDENTIFY THE BASIC ETHICAL PRINCIPLES WHICH SHOULD UNDERLIE THE CONDUCT OF BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS
- DEVELOP GUIDELINES TO ASSURE THAT SUCH RESEARCH IS CONDUCTED IN ACCORDANCE WITH THOSE PRINCIPLES

National Research Act, 1974 (PL 93-348)

NATIONAL RESEARCH ACT

- 1974
- DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
- NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, 1975-1978
  - 125 RECOMMENDATIONS IN 17 DIFFERENT REPORTS FOR THE CONDUCT OF RESEARCH INVOLVING HUMANS

The Belmont Report

Respect for Persons - informed consent: *information, comprehension, voluntariness*

Justice - selection of subjects: *vulnerable populations*

Beneficence - assessment of risks and benefits:

identify both nature and scope systematic evaluation

1972	U.S. Department of Health, Education, and Welfare guidelines for its programs
1974	U.S. Department of Health, Education, and Welfare regulations, 45 Code of Federal Regulations, Part 46, Subpart A
1975	U.S. Department of Health and Human Services (DHHS) regulations, 45 Code of Federal Regulations, Part 46, Subparts B,C,D (revised in 1981 in concert with FDA regulations)
1985	Public Law 99-158 establishes institutional review to protect the rights of human subjects in federally funded biomedical and behavioral research
1991	Common Rule: 17 Federal agencies adopt same regulations for their programs FDA food and drug regulations
2018	2018 Requirements, "*The New Rule*" Revised January 19, 2017 and amended on January 22, 2108 and June 19, 2018.

INTERNATIONAL ETHICS OVERSITE

	established
Nuremberg Code	1948
Declaration of Helsinki.	1964
International Conference on Harmonization (ICH)	1990
Ethical Guidelines from Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)	2002
European Union General Data Protection Regulation (GDPR)	2018

Most Countries have their own Ethics Committees and Guidelines

HUMAN SUBJECTS PROTECTION REGULATIONS & OTHER

- INFORMED CONSENT OF SUBJECTS
- ETHICAL REVIEW OF RESEARCH BY INSTITUTIONAL REVIEW BOARDS (IRBS)
- INSTITUTIONAL ASSURANCE OF COMPLIANCE
- CODE OF ETHICS- ASSOCIATIONS & ORGANIZATIONS
- GINA (GENETIC INFORMATION NONDISCRIMINATION ACT)
- STATE LAWS (NH PROTECTION MENTALLY ILL)
- INTERNATIONAL PROTECTION-GDPR

Risk vs. Benefit

Individual
Group
Society

Privacy- control over the extent, circumstances of sharing oneself with others (behavior, intellect, physical self)

Confidentiality- treatment of information disclosed in a relationship of trust.

Deception?

Risks to research participants that may produce ethical concerns

- Physical
- Psychological/ Emotional or “interaction risks”
  - discomfort or embarrassment (sensitive topic?)
  - Unexpected insight into one’s flaws
- Social or “informational risks”
  - stigma
  - embarrassment
  - social standing
  - other effects on personal life and relationships
- Financial or economic risks
  - employment or insurance eligibility
  - legal
- Risks specific to vulnerable populations

PROTECTIONS (MINIMIZE RISK)

INTERACTION:

NOTICE OF INFORMATION TOPIC IN ADVANCE

-PARTICIPANTS CAN SELF-SELECT

RECRUITMENT/EXCLUSION

DESIGN FOR SENSITIVITY IN DISCUSSION, ABILITY TO END CONVERSATION

INFORMATION:

PSEUDONYMS OR CODES,

DATA PROTECTIONS (PAPER AND ELECTRONIC, SHORT AND LONG-TERM)

CONTROLLED ACCESS

INDIVIDUAL IDENTIFYING CHARACTERISTICS

CERTIFICATE OF CONFIDENTIALITY

NIH National Institutes of Health
Office of Extramural Research

CPHS

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

- DARTMOUTH COLLEGE
- RELYING AGREEMENTS WITH:
  - OTHER ACADEMIC INSTITUTIONS
  - HOSPITALS OR HEALTH CLINICS
  - START UP COMPANIES

PROCESS OF ETHICAL REVIEW OF STUDENT RESEARCH AT DARTMOUTH COLLEGE:

Classroom Coursework or Assignments	Independent student projects, theses, etc.
Receive review via your Professor or instructor	Receive review from your faculty advisor, and Committee for the Protection of Human Subjects (CPHS)

WHAT DOES THE PROCESS LOOK LIKE WHEN A PROJECT NEEDS REVIEW?

Research? Regulatory definition

Research **means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.**

Research? yes

- Human subject involved?

Human subject **means a living individual about whom an investigator (whether professional or student) conducting research obtains:**

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Not Human Subject?

-Study involved de-identified data

-Study involves data from people no longer living

Exempt from IRB review?

Categories include:
- Research that only includes survey procedures, interview procedures, or observation of public behavior
- Research involving benign behavioral interventions in conjunction with the collection of information
- Secondary research data and information

Research? Regulatory definition

yes

Human subject involved? Regulatory definition

yes

Exempt from IRB review? 8 categories

no

Eligible for expedited review? Minimal risk?

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

EXPEDITED CATEGORIES

-**Category #2**: Collection of **blood samples** by finger stick, heel stick, ear stick, or venipuncture …
- **Category #3**: Prospective collection of **biological specimens** for research purposes by noninvasive means.
- **Category #4**: Collection of data through **noninvasive procedures** routinely employed in clinical practice…
- **Category #5**: Research involving materials (**data,** documents, records, or specimens)…
- **Category #6**: Collection of data from **voice, video, digital, or image recordings** made for research purposes
- **Category #7:** Research on individual or group characteristics or **behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing **survey, interview**, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Research?	yes
Human subject involved?	yes
Exempt from IRB review?	no
Eligible for expedited review?	No

IRB review at convened meeting

REGULATORY CRITERIA FOR REVIEW

-SCIENTIFIC DESIGN APPROPRIATE

-MINIMIZE RISKS AND MAXIMIZE BENEFITS TO PARTICIPANTS

-RISK-BENEFIT ASSESSMENT FOR PARTICIPANTS

-APPROPRIATE AND EQUITABLE SELECTION OF PARTICIPANTS

Regulatory Criteria for Review: Informed Consent

A process, not a document → Permission

-RESEARCH PURPOSE

-DURATION OF PARTICIPATION

-DESCRIPTION OF PROCEDURES, RISKS, BENEFITS

-ALTERNATIVES TO PARTICIPATION

-EXTENT OF CONFIDENTIALITY OF RESEARCH RECORDS

-CONTACT INFORMATION FOR INVESTIGATOR

-ASSURANCE OF A RIGHT TO WITHDRAW

-ASSURANCE OF VOLUNTARINESS

-AUTHORIZATION FOR RESEARCH USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION.

Regulatory Criteria for Review: Informed Consent

ALTERATIONS AND WAIVERS OF CONSENT OR AUTHORIZATION REQUIRE JUSTIFICATIONS BY THE INVESTIGATOR THAT SATISFY SPECIFIC REGULATORY CRITERIA

- OF ENTIRE CONSENT PROCESS AND/OR DOCUMENTATION
- OF SIGNED CONSENT DOCUMENT

SURVEYS, INTERVIEW PROCEDURES

- STUDY DESIGN TO ENSURE SAMPLE SURVEYED OR INTERVIEWED IS APPROPRIATE.
- HOW WILL SURVEYS BE DISTRIBUTED AND COLLECTED?
- TYPES OF QUESTIONS BEING ASKED?
  - SENSITIVE QUESTIONS? POTENTIAL FOR INTERVIEWEE DISCOMFORT? INFORMATIONAL RISKS?
- ARE SURVEYS ANONYMOUS?
- TRY TO ANTICIPATE DIFFICULT SITUATIONS AND BE PREPARED.

SURVEYS, INTERVIEW PROCEDURES

- POTENTIAL PARTICIPANTS SHOULD BE AWARE OF:
  - YOUR NAME AND AFFILIATION WITH DARTMOUTH
  - THE REASON FOR THE PROJECT
  - THE LEVEL OF CONFIDENTIALITY OF RESPONSES
  - THE VOLUNTARY NATURE OF THE PROJECT.

International setting and other cultures:

- Consent
- Autonomy
- Role of individual in society/group
- Vulnerability
- Laws

Who can help with context?

Experienced researchers, consultants, faculty advisor, local ethics boards, universities, aid organizations

INTERNATIONAL CONSIDERATIONS

- Rationale for conducting research
- Local Ethics Committee
- Knowledge of relevant laws, regulations, guidance and customs
- Mechanisms for communicating

Risks acceptable in the social context of the host country?

If compensation is being offered is it appropriate for the setting?

Will the results of the research be used at the host site?

What about GDPR?

A LIST OF COUNTRIES THAT HAVE IMPLEMENTED THE GDPR:

- AUSTRIA
- BELGIUM
- BULGARIA
- CROATIA
- REPUBLIC OF CYPRUS
- CZECH REPUBLIC
- DENMARK
- ESTONIA
- FINLAND
- FRANCE
- GERMANY
- GREECE
- HUNGARY
- ICELAND
- IRELAND
- ITALY
- LATVIA
- LIECHTENSTEIN
- LITHUANIA
- LUXEMBOURG
- MALTA
- NETHERLANDS
- NORWAY
- POLAND
- PORTUGAL
- ROMANIA
- SLOVAKIA
- SLOVENIA
- SPAIN
- SWEDEN
- UNITED KINGDOM

POINTS TO REMEMBER:

-CONSIDER AND PREVENT ANY EXPLOITATION OR HARM TO INTERVIEWEES /PARTICIPANTS

-CONDUCT PROJECT IN A PROFESSIONAL MANNER.

-BE WELL GROUNDED IN THE BACKGROUND OF SUBJECTS

-TREAT POTENTIAL PARTICIPANTS WITH RESPECT

-TELL CPHS ABOUT YOUR PROJECT *BEFORE* YOU START!

-LET US KNOW IF ACTIVITIES CHANGE AND WHEN STUDY ACTIVITIES ARE COMPLETE

WHAT CPHS NEEDS FOR REVIEW

- FUNDING OR OTHER PROPOSAL DOCUMENT
- STUDY PLANS:
  - DESCRIPTION OF THE PROPOSED RESEARCH ACTIVITIES
  - RECRUITMENT OF PARTICIPANTS (POSTERS, ADS, ETC.)
  - CONSENT PROCESS AND DOCUMENTS
  - PROTECTION OF PRIVACY
  - DATA MANAGEMENT, INCLUDING MAINTENANCE OF CONFIDENTIALITY, SECURITY, AND INCIDENTAL FINDINGS

  INTERNATIONAL FORM
- INSTRUMENTS
  - SURVEY QUESTIONS , INTERVIEW QUESTIONS

CPHS WEBSITE
www.dartmouth.edu/~cphs

Office for Human Research Protection
US Department of Health and Human Services
http://www.hhs.gov/ohrp/

Thank You!

USE THE LINK BELOW TO CERTIFY THAT YOU HAVE FULFILLED THE IRB'S EDUCATION REQUIREMENT.
USE YOUR NETID AND ASSOCIATED PASSWORD TO LOG IN.

HTTPS://DARTMOUTH.CO1.QUALTRICS.COM/JFE/FORM/SV_0P64SY51Z0BJJ13