

IRB Supported Research

05-499/899 Fall 2024

Celebrating Accessibility

<https://cmu-05-499.github.io>

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Administrivia

- We have multiple visitors today
 - Nicole Lockerman, CEO SocialWise VR and the University School
 - Jazmil Baez, from the Western PA School for Blind Children
- In-class project pitches next week on Tuesday, P1 on the website Client Descriptions Available on Canvas - <https://canvas.cmu.edu/courses/42586/files?preview=11572962>
- Who is going to Grace Hopper Conference next week?
- Need a reading discussant for Thursday

Research with Human Subjects

Human Subjects Research

Many different goals

- Find out more about human behavior

- Check the quality or efficacy of software / device

- Compare software / device

Important factors

- Research should be ethical**

- How to get the right information

- How to measure the right information

- How to analyze the right information

Ethical Consideration

Sometimes tests can be **distressing**

You have a **responsibility to alleviate that stress**

- make voluntary with informed consent

- avoid pressure to participate

- let users know they can stop at any time

- offer breaks

- stress you are testing the system, not the user

- make collected data as anonymous as possible

Often must get **human subjects approval**

What is an Institutional Review Board? Why do we need it?

The Readings

1. The 1979 Belmont Report
2. Institutional review board (IRB) and ethical issues in clinical research
3. The Milgram Experiment: Obedience to Authority

Too Many Examples of Ethical Research Failures

WWII Experimentation
Nuremberg Trials 1947

Milgram Study 1960s

Stanford Prison Experiment 1971

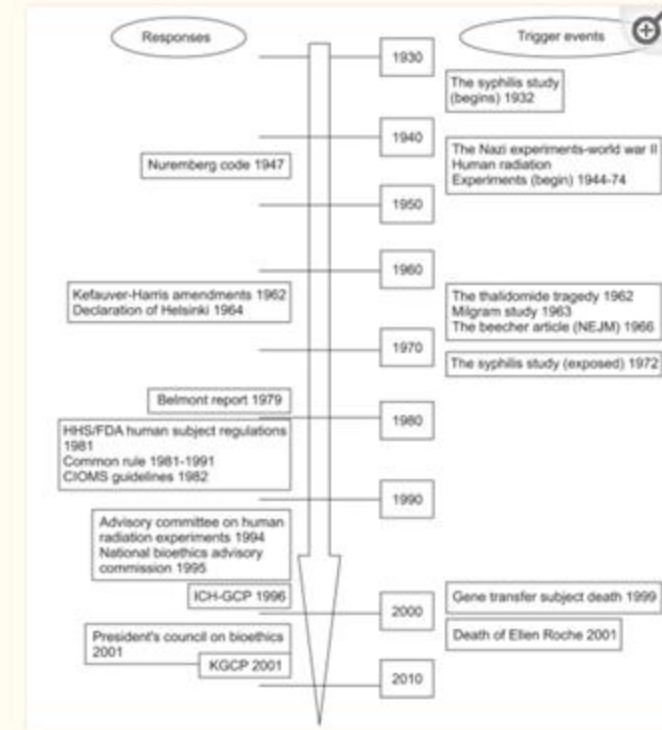


Fig.1

Chronicle of scandals and responses are presented.

Milgram Obedience Experiment (1960s)

Before the establishment of IRBs

Very distressing to participants, significant deception involved



Tuskegee Syphilis Study (1932-1972)

US Public Health Service (PHS) ran study on syphilis for 40 years!

399 low-income black men told they were being treated for “bad blood.”

They actually had syphilis and were left untreated

Local physicians given lists of people not to treat

Original study only meant to last 6-9 months



<https://www.britannica.com/event/Tuskegee-syphilis-study>

Tuskegee Syphilis Study (1932-1972)

Initially no syphilis treatment available, but by 1947, penicillin, the standard treatment, was withheld

Men died. Their families got infected.

For participating in the study, the men were given free medical exams, free meals and transportation, and free burial insurance

Stopped in 1972 after PHS employees leaked info to the press

"I don't know what they used us for. I ain't never understood the study." - a survivor

National Research Act (1974)

1974 National Research Act (Pub. L. 93-348)

Direct response to Tuskegee study

Established the “National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research”

- Identify basic ethical principles

- Develop guidelines to assure research is carried out according to those principles

Required IRBs at institutions receiving support for human subjects research for Health, Education, and Welfare within Dept. of Health and Human Services

February 1976 - Held four-day conference at Smithsonian Institution’s Belmont Conference Center

Belmont Report (1979)

3 core principles

1. **Respect for persons** - protecting the autonomy of human subjects
2. **Beneficence** - protecting participants from harm
3. **Justice** - protecting human subjects from exploitation

Federal Regulations

Basic Ethical Principles

Respect for Persons



Beneficence



Justice



Applications

Informed Consent

Assessment of Risk and Benefits

Minimize Risk

Protect vulnerable

Fair selection of Subjects

System of Institutional Review Boards (IRBs) to monitor human subject research

Federal regulations for treatment of human subjects

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

General Process - Designing a Study

Define the **goals** for your study - What do you want to learn?

Choose participants

Define the **procedures/tasks** for each group of participants

What will you ask participants to do?

What kind of **data** do you need to collect?

General Process - Designing a Study

Recruiting Participants

Questionnaires - Pre/Post Test

Recordings

Compensation

Risks/Benefits

Protecting the Participants

Protecting the Data

General Process - Designing a Study

Informed Consent

- Providing Enough Information

- Ensuring the information is understood

- Documenting voluntary consent to participate

Participation Activity

Is this ethical?

Facebook “Mood Manipulation Study” (2012)

“Facebook’s data scientists manipulated the News Feeds of **689,003 users, removing either all of the positive posts or all of the negative posts** to see how it affected their moods. If there was a week in January 2012 where you were only seeing photos of dead dogs or incredibly cute babies, you may have been part of the study.”

“The researchers ... found that **emotions were contagious**. When positive expressions were reduced, people produced fewer positive posts and more negative posts; when negative expressions were reduced, the opposite pattern occurred”

Automated testing “**was consistent with Facebook’s Data Use Policy**, to which all users agree prior to creating an account on Facebook, constituting informed consent for this research.”

<http://www.forbes.com/sites/kashmirhill/2014/06/28/facebook-manipulated-689003-users-emotions-for-science/>

<http://www.forbes.com/sites/gregorymcneal/2014/06/30/controversy-over-facebook-emotional-manipulation-study-grows-as-timeline-becomes-more-clear>

Participation Activity

- Pair up with a neighbor and write your names on a piece of paper.
- Was the “Mood Manipulation Study” Ethical?
 - Write down 2 reasons for why it should be considered ethical.
 - Write down 2 reasons why it should NOT be considered ethical.
- Pair up with another pair and discuss, see if you can come to consensus on whether it was an ethical study.
- Then we will discuss as a class.

Turn in your papers at the end of class

SocialWise VR

- Nicole Lockerman, CEO
- SocialWise VR (SWVR) is an on-demand social skill virtual reality application that is noteworthy for being the first VR social skill curriculum to be recorded with live actors. SWVR presents users with social challenges in a “choose your own adventure” style curriculum and offers interactive VR scenarios where users can practice real-life social interactions in a controlled and supportive environment. The platform focuses on building communication skills, confidence, and social awareness through immersive and engaging activities. By leveraging VR technology, SocialWise VR aims to provide a unique and effective tool for social learning and personal growth.

The University School

- Nicole Lockerman
- The University School, founded in 1911 and located in Shadyside, provides a progressive and individualized high school experience to neurodivergent students in grades 9-12. With a commitment to academic excellence and personal growth, The University School offers a diverse curriculum that integrates rigorous academics with social-emotional development. The school community is characterized by its supportive environment, strong values, and dedication to nurturing each student's unique potential.

LAVI - Western PA School for the Blind

- Jazmil Baez, Program Specialist
- The Learning Adventures for the Visually Impaired, or LAVI for short, is an adult training facility located on the campus of The Western Pennsylvania School for Blind Children in Oakland. What sets our program apart from other adult programs is our ability to provide specialized services to our participants as well as someone to monitor their medical needs. We serve a community of individuals with a range of visual needs and a wide range of complex medical needs. Every day we keep to a schedule packed with different activities from adapted gym, music therapy, art class, to social group, morning meeting, and community participation supports. As the weather cools, our opportunities to explore the community decrease to ensure the health and safety of our participants. Therefore, it's important for us to take advantage of the technology the facility has to offer.