Ethics and Protecting *Human Subjects*

Trigger Warning:

Some images in this presentation depict immoral or unethical medical experiments [See Presentation without Pictures]

Why are we talking about ethics?

… this is a class about UX Design and Human-computer Interaction…

- … why are ethics important for our work?
- … why do we need to talk about ethics in this class?

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- … why are ethics important for our work?
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Because we work with People

For example…

…when we work with **people with disabilities** (or diverse abilities)

For example…

…when we work with minors or **children** or other **vulnerable groups**

so what…where ethics ever an issue?

Question

Did we (researchers, experimenters) ever mess up working with other people?

so what…where ethics ever an issue?

Question

Did we (researchers, experimenters) ever mess up working with other people?

Yes, we did mess up … a lot!

so what…where ethics ever an issue?

As a result, people were **hurt** both, **psychologically** and **physically** and **suffered permanent** and potential **lethal outcomes.**

https://www.verywellmind.com/thmb/8_od0SLmLGheZxR-oagtitSpqf8=/4000x3000/filters:fill(ABEAC3,1)/5727759849_685be7a535_o-56a793f05f9b58b7d0ebdb27.jpg
https://psmag.com/.image/t_share/MTI3NTgxOTY0MzM2NDcwNDk0/essays-culture-1.jpg

For example, Milgram Study (1961-1963)

Public Announcement

WE WILL PAY YOU $4.00 FOR ONE HOUR OF YOUR TIME

Persons Needed for a Study of Memory

*We will pay five hundred New Haven men to help us complete a scientific study of memory and learning. The study is being done at Yale University.

*Each person who participates will be paid $4.00 (plus 50c carfare) for approximately 1 hour's time. We need you for only one hour: there are no further obligations. You may choose the time you would like to come (evenings, weekdays, or weekends).

***No special training, education, or experience is needed. We want:**

Factory workers	**Businessmen**	**Construction workers**
City employees	**Clerks**	**Salespeople**
Laborers	**Professional people**	**White-collar workers**
Barbers	**Telephone workers**	**Others**

All persons must be between the ages of 20 and 50. High school and college students cannot be used.

*If you meet these qualifications, fill out the coupon below and mail it now to Professor Stanley Milgram, Department of Psychology, Yale University, New Haven. You will be notified later of the specific time and place of the study. We reserve the right to decline any application.

*You will be paid $4.00 (plus 50c carfare) as soon as you arrive at the laboratory.

TO:
PROF. STANLEY MILGRAM, DEPARTMENT OF PSYCHOLOGY, YALE UNIVERSITY, NEW HAVEN, CONN. I want to take part in this study of memory and learning. I am between the ages of 20 and 50. I will be paid $4.00 (plus 50c carfare) if I participate.

NAME (Please Print). . . . . .

ADDRESS . . . . . .

TELEPHONE NO. . . . . Best time to call you . . . . . .

AGE . . . . . OCCUPATION . . . . . SEX . . . . . .
CAN YOU COME:

WEEKDAYS . . . . . EVENINGS . . . . . WEEKENDS . . . . . .

On the left is an ad for a *study of Memory*.

(https://youtu.be/Kzd6Ew3TraA)

https://en.wikipedia.org/wiki/Milgram_experiment

For example, Stanford Prison Experiment (1971)

https://exhibits.stanford.edu/spe/catalog/sk516df1347

For example, Stanford Prison Experiment (1971)

On the right is an ad for a *study of prison life*.

The ad does not mention being *screamed at, being arrested, being stripped nude, being chained, being locked a small closet for solitary confinement* and *being forced to clean toilets* with your bare hands.

Male college students needed for psychological study of prison life. $15 per day for 1-2 weeks beginning Aug. 14. For further information & applications, come to Room 248, Jordan Hall, Stanford U.

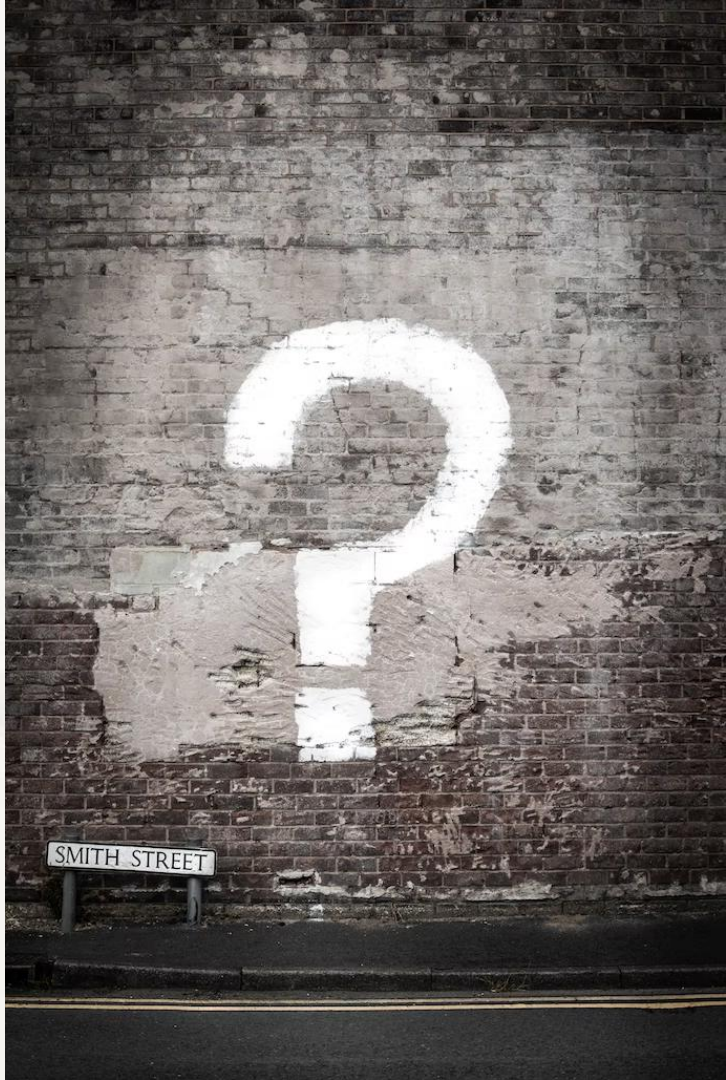
https://exhibits.stanford.edu/spe/catalog/sk516df1347

What are ethics?

Before reviewing a history of unethical behavior and experiments, and resulting changes, let's first think about ethics?

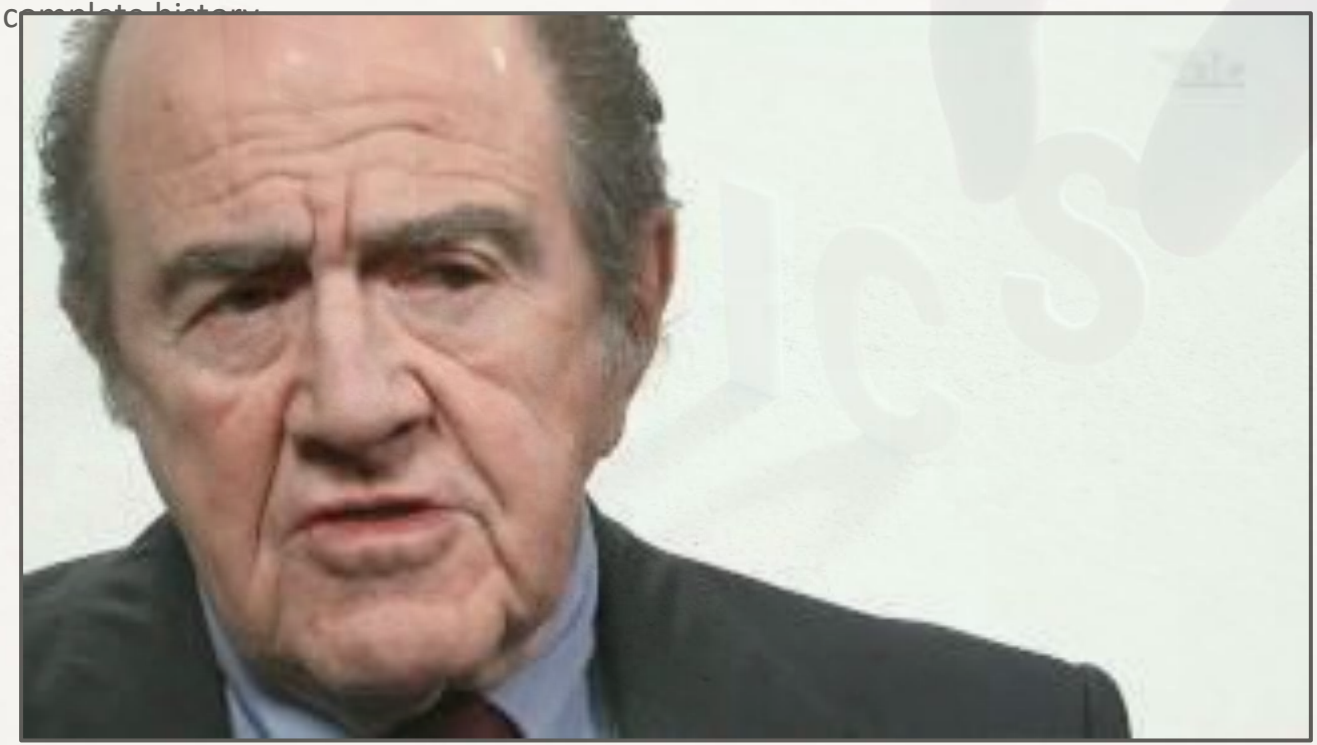
- What are ethics?
- What does it mean to be — or act — ethically or unethical, generally speaking?
- What does it mean to conduct an i) ethical or ii) unethical study with human participants?

Any ideas or thoughts?



Toward ethical research practices and codes

A short and incomplete history:



Toward ethical research practices and codes

A short and incomplete history

- Nuremberg Code (1948)
- Kefauver Amendments (1962)
- Declaration of Helsinki (1964)
- National Research Act (1974)
- Belmont Report (1979)
- The Common Rule (1981)

U. S. Department of Health, Education, and Welfare

Food and Drug REVIEW

Issued by the Food and Drug Administration

Vol. 46 November 1962 No. 11

PRESIDENT KENNEDY SIGNS NEW DRUG AMENDMENTS

Observers are, from left to right, Senator Thomas J. Dodd, Dr. Frances Kelsey, Commissioner Larrick, Senator Philip A. Hart, Senator Hubert H. Humphrey, Senator Estes Kefauver, Senator Olin D. Johnston, Under Secretary Ivan Nestingen, Congressman Leo W. O'Brien, and Congressman Kenneth A. Roberts.

On signing the Amendments on October 10, the President made the following statement:

"I am pleased to approve this bill, which is designed to provide safer and more effective drugs to the American consumer. Enactment of this legislation will help give the American consumer the protection from unsafe and ineffective drugs. It will also insure that our pharmaceutical industry will be even better equipped to provide us with the best possible drugs to be found anywhere.

"The Congress is to be congratulated in moving so quickly. Fortunately, prior to the revelation of the dangers posed by drugs like thalidomide, the foundation for legislative action on drugs had been laid down in exhaustive

(continued on next page)

https://twitter.com/us_fda/status/652205035129040896

Nuremberg Code

Established 1948, as a result of German War Crimes and medical experiments in the 1930s-1940s

What happened:

- Medical experiments on thousands of people without their consent
- 23 Germans tried for war crimes regarding unethical experiments, 16 were found guilty

https://www.dailymail.co.uk/news/article-2518619/Winter-camps-Holocaust-survivor-died-Auschwitz-worked-concentration-camps-aged-just-13-recalls-bitterest-months-Nazi-persecution.html

Nuremberg Code

Outcomes of the NC:

- A ten point statement delimiting permissible medical experimentation on human subjects
- **Voluntary** human subject **consent** is **absolutely essential** (voluntary participation and informed consent)

Nuremberg Code

The Nuremberg Military Tribunal's decision in the case of the United States v Karl Brandt et al. includes what is now called the Nuremberg Code, a ten point statement delimiting permissible medical experimentation on human subjects. According to this statement, humane experimentation is justified only if its results benefit society and it is carried out in accord with basic principles that "satisfy moral, ethical, and legal concepts."

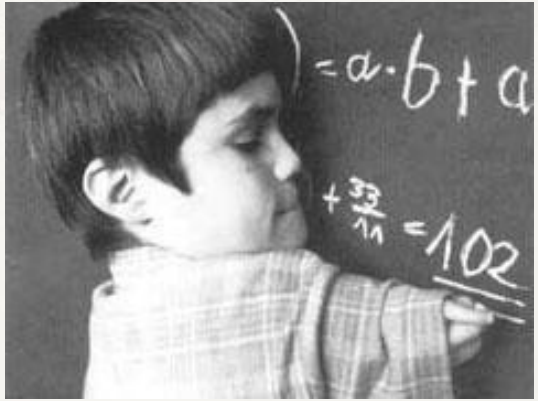
—"Permissible Medical Experiments." Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg October 1946 – April 1949, Washington. U.S. Government Printing Office (n.d.), vol. 2., pp. 181-182.

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion, and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires

Kefauver Harris Amendments

Established 1962

- Late 1950s pregnant women given thalidomide to reduce nausea and help with sleep
- Patients did not know thalidomide was not FDA approved
- Over 12,000 babies born with deformities



https://www.itv.com/news/calendar/2017-03-03/family-appeal-for-answers-over-thalidomide-baby-death
https://theconversation.com/why-thalidomide-survivors-have-such-a-tough-time-getting-compensation-47164

Kefauver Harris Amendments

Outcomes:

- Studies must assess risks and benefits
- Drug manufacturers must prove to FDA the effectiveness before marketing
- Introduced *"proof-of-efficacy"* standard for drugs

Commonly called the Kefauver-Harris Amendments, they were sponsored in Congress by Sen. Estes Kefauver (D-Tenn.) and Rep. Oren Harris (D-Ark.). Once signed into law by President Kennedy on Oct. 10, 1962, the amendments established a framework that required drug manufacturers to prove scientifically that a medication was not only safe, but effective.

FDA Commissioner Margaret Hamburg, M.D., notes that the 1938 FD&C Act had serious shortcomings at that time. For example, manufacturers could sell a drug if the FDA didn't act within 60 days to prevent its marketing. And FDA had no authority to enforce good manufacturing processes.

"With the passage of the amendments, FDA was no longer a helpless bystander while unproven medicines were streaming into pharmacies and onto patients' bedside tables," says Hamburg.

Declaration of Helsinki

Established 1964

- Was iterated on since WWII

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

Outcomes:

- Participants can only give consent once they are fully informed;
- prioritize participant health;
- be aware of “special populations”, indigenous or vulnerable populations (prisoners).

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

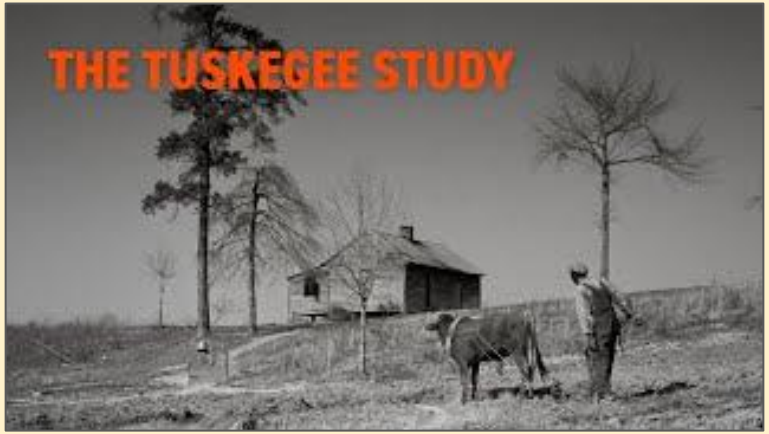
All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Example: Tuskegee Syphilis study

Belmont Report and IRB Creation

National Research Act (1974) & Belmont Report (1979) led foundation for Institutional Review Board (IRBs)



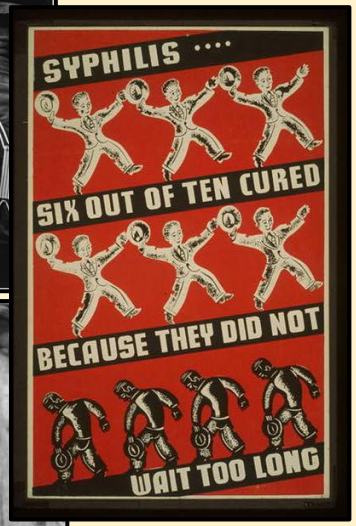
Based on review of the Tuskegee Syphilis study, an unethical experiment conducted by the US Government from 1932 — 1972

Example: Tuskegee Syphilis study

Belmont Report and IRB Creation

The goal was to "observe the natural history of untreated syphilis" in black populations, but the subjects were completely unaware and were instead told they were receiving treatment for bad blood when in fact, they received no treatment at all.

https://www.mcgill.ca/oss/article/history/40-years-human-experimentation-america-tuskegee-study



Tuskegee Syphilis study

- In 1932, 400 black, poor, low literacy sharecroppers had syphilis
- In 1947 penicillin was invented… participants were not offered it
- Study was not stopped until 1973!

https://www.mcgill.ca/oss/article/history/40-years-human-experimentation-america-tuskegee-study
https://www.joshuakennon.com/the-tuskegee-experiment/
https://commons.wikimedia.org/wiki/File:Syphilis-poster-wpa-cure.jpg

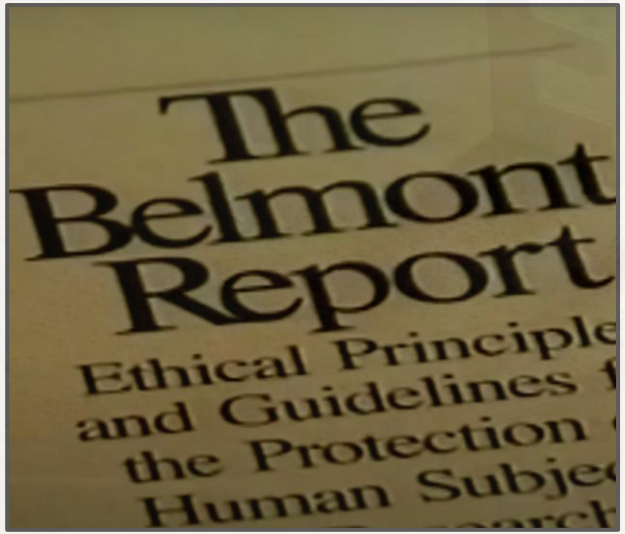
Belmont Report and IRB Creation

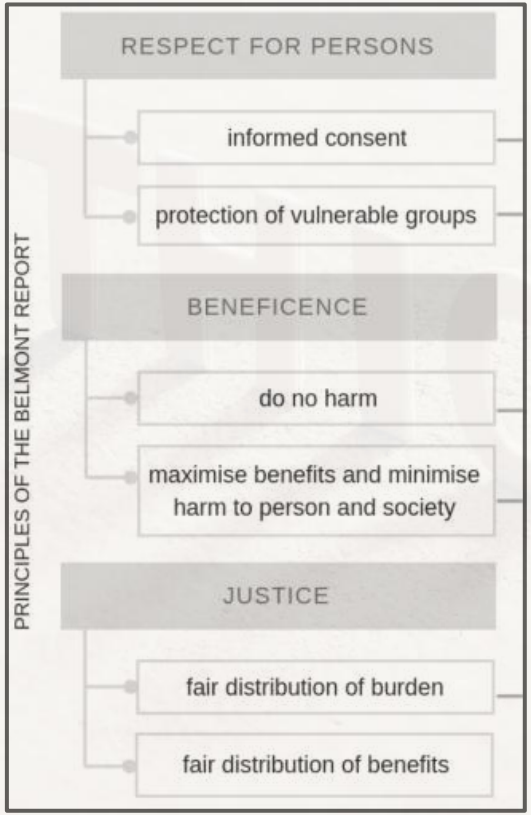
National Research Act (1974) & Belmont Report (1979) led foundation for Institutional Review Board (IRBs)

Outcomes:

- Informed consent;
- Independent review;
- Risks should not exceed benefits;
- Protect human subjects

Ethical Considerations from the Belmont Report





Anabo, I.F., Elexpuru-Albizuri, I. & Villardón-Gallego, L. Revisiting the Belmont Report's ethical principles in internet-mediated research: perspectives from disciplinary associations in the social sciences. *Ethics Inf Technol* 21, 137–149 (2019).
https://doi.org/10.1007/s10676-018-9495-z

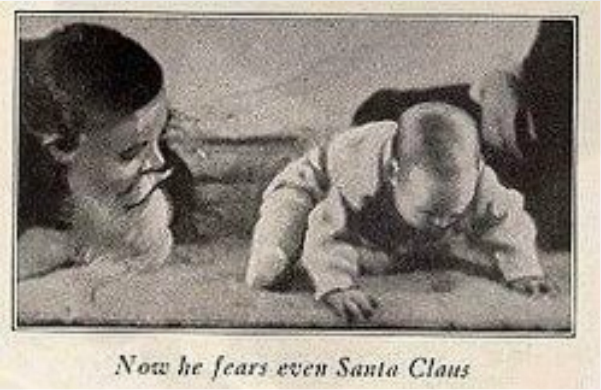
The Common Rule

Iterating on Belmont Report

- Special considerations for pregnant people (1978) and prisoners (1978)

More reports and considerations for…

- … people developing nations (1982)
- … children (1983), and
- … people with mental health considerations (1999)

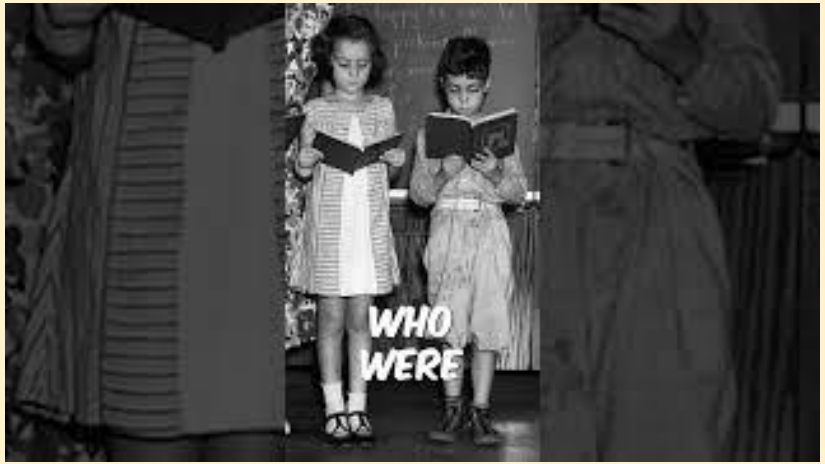


https://images.newscientist.com/wp-content/uploads/2014/10/dn26307-1_300.jpg
https://upload.wikimedia.org/wikipedia/commons/c/cc/Little-albert.jpg

Example: Monster Study

A stuttering / reinforcement experiment on 22 orphan children at the University of Iowa.

- 1939: Conducted by Wendell Johnson, lasting about 6 months
- 2001: University of Iowa apologizes
- 2007: 7 orphan children were awarded $1.2M US Dollar "by the State of Iowa for lifelong psychological and emotional scars caused by six months of torment during the University of Iowa experiment."
  https://en.wikipedia.org/wiki/Monster_Study#cite_note-2



Key
Takeaways

Applied Ethics in HCI

In course, in other research contexts as well as in professional settings

1. **Remember, we work with People in HCI/d**
2. **Full Disclosure**
3. **Anonymity & Confidentiality**
4. **Informed Consent**
5. **Voluntary Participation & Early Termination**
6. **Incentives upon Completion**

Applied Ethics in HCI

1. Remember, we work with People in HCI/d

For your research(Interviews, Observations, User Tests), keep the **following guidelines in mind**.

Applied Ethics in HCI

2. Full Disclosure

Explain to your participants **what is going to happen** before the study, for instance, if you want to record them, ask them if that is ok or not.

Applied Ethics in HCI

3. Anonymity & Confidentiality

Is data **anonymized** or if not, is **personally identifiable information** kept **confidential**. Who has **access** to it? How will it be **shared**?

Applied Ethics in HCI

4. Informed Consent

Ask your participants if they have **any questions or concerns** before the study.

If they do, address them.

Applied Ethics in HCI

5. Voluntary Participation & Early Termination

Make it clear to your participants that **they can ask questions**, take a **break**, or even **end the study** at any time, if they want to.

Applied Ethics in HCI

6. Incentives upon Completion

If you offer **compensation**, you may **consider** the actual **payout** based on the p**articipant's study completion.**