Research Ethics

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Participants and their Recruitment

Three key questions when thinking about participant recruitment:

1. An Ethical Question: How *should* we treat them?
2. A Theoretical Question: *Who* do we want to recruit?
3. A Practical Question: *How* do we recruit them?

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What is research ethics?

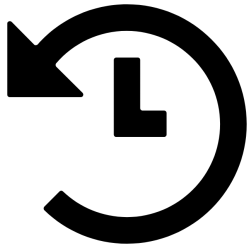
Research Ethics

Guidelines for conduct and behavior of researchers that maximize benefits and minimize harm to participants (Weinbaum et al., 2018).

At minimum, the purpose of ethical research is:

- Protecting participants from physical and psychological harm.
- Providing freedom of choice about participating in the research.
- Maintaining awareness of the power differentials between researcher and participant
- Providing informed consent, and honestly describing research to participants

Why do we need a code for ethical research?



Nuremberg Code (1947)

Nuremberg Trials

10 rules of medical research conduct developed in response to Nazi research atrocities:

1. Voluntary consent is essential
2. The results of any experiment must be for the greater good of society
3. Human experiments should be based on previous animal experimentation
4. Experiments should be conducted by avoiding physical/mental suffering and injury
5. No experiments should be conducted if it is believed to cause death/disability
6. The risks should never exceed the benefits
7. Adequate facilities should be used to protect subjects
8. Experiments should be conducted only by qualified scientists
9. Subjects should be able to end their participation at any time
10. The scientist in charge must be prepared to terminate the experiment when injury, disability, or death is likely to occur

Declaration of Helsinki (1964)

Expanded on the Nuremberg Code in 1964 and required journal editors to ensure published research was compliant

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

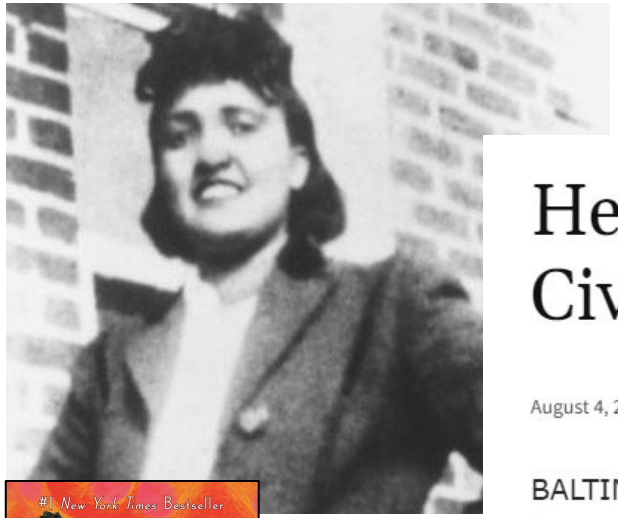
WORLD MEDICAL ASSOCIATION

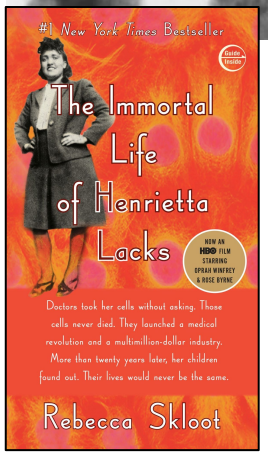
Tuskegee Experiment (1932-1972)

40 Years of Human Experimentation in America: The Tuskegee Study

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.

Henrietta Lacks (1920-1951)





Henrietta Lacks' Family Hires Prominent Civil Rights Lawyer

August 4, 2021

BALTIMORE (AP) – The family of a Maryland woman who unwittingly spurred a research bonanza when her cancer cells were taken without her knowledge in 1951 has hired a prominent civil rights lawyer to seek compensation from pharmaceutical companies.

https://seattlemedium.com/henrietta-lacks-family-hires-prominent-civil-rights-lawyer/

Belmont Report

- National Research Act creates the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974)
- The Commission drafts the Belmont Report (1978)

THE BELMONT REPORT

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Belmont Report

Defines the principles and applications that apply to medical and behavioral research investigations

Three basic ethical principles

Beneficence
Research should confer benefits, with minimal risks, as determined by a risk-benefit analysis

Autonomy
(respect for persons)
Participants are treated as autonomous and can exercise informed consent.

Justice
Benefits and risks of research should be allocated fairly when selecting research subjects.

APA Ethics Code (2017)

Applies specifically to psychologists in their various roles, first created in 1953.

Beneficence and nonmaleficence
Research should maximize benefits and minimize any possible harmful effects of participation

Fidelity and responsibility
Psychologists establish relationships of trust with those with whom they work

Integrity
Psychologists seek to promote accuracy, honesty, and truthfulness in the science, teaching, and practice of psychology

Justice
Psychologists recognize that fairness and justice entitle all persons

Respect for Persons
Psychologists are aware that special safeguards may be necessary to protect the rights and welfare of some persons or communities

How do we (practically) conduct ethical research?

Ethical Principles

Ethical principles fall into three major categories:

- Ethical scientific inquiry
- Ethical conduct and behaviors of researchers
- Ethical treatment of research participants

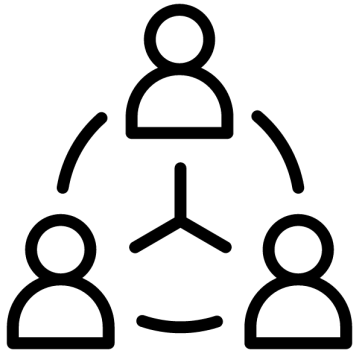
(Weinbaum et al., 2022)

Ethical scientific inquiry

(Weinbaum et al., 2022)

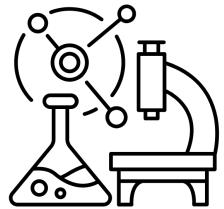
Ethical Scientific Inquiry

- Principle: Duty to Society
- The research inquiry itself must benefit society.
- Research must not be undertaken if there is no benefit to society.



(Weinbaum et al., 2022)

Ethical conduct and behaviors of researchers



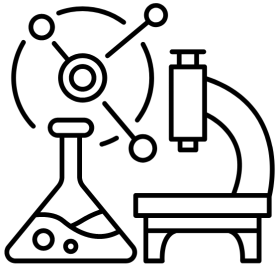
(Weinbaum et al., 2022)

Ethical conduct and behaviors of researchers

Researchers should conduct themselves in certain manners, and they are responsible for their knowledge and awareness of ethics and appropriate research methods.

Training at Individual Level

CITI PROGRAM



(Weinbaum et al., 2022)

Some unethical practices and safeguards

Conflict of Interest
When a researcher's secondary interests (financial, personal) shape their research practices.

Safeguard
Journals require researchers to disclose any COI upon article submission.

Plagiarism
Theft or misappropriation of someone else's words, ideas, intellectual contribution.

Safeguard
Peer-review process

Some unethical practices and safeguards

Co-authorship
In papers with multiple authors, it's unclear who contributed what, and institutions/researchers are occasionally unduly credited.

Safeguard
Journals require authors to submit a document outlining each authors' contribution along with their article.

Falsification/Fabrication
Researchers exclude, alter, or intentionally misinterpret data to produce a significant result.

Safeguard
Peer-review process, pre-registration, open data.

Ethical treatment of research participants

(Weinbaum et al., 2022)

Institutional Review Boards (IRBs)

Any institution that receives federal funds must have an IRB that is responsible for reviewing research at that institution.

- Must have minimum five members
- One must be an external member

Human-subjects research conducted by students, faculty and staff must be reviewed and approved by the IRB before the start of the research.

E.g. of a Typical IRB Review Process

IRB Decision is Required Prior to Contacting Participants or Collecting Data

(https://ualr.edu/irb/)

Institutional Review Boards (IRBs)

The IRB reviews every detail of your study, including:

- The theoretical framework & hypotheses
- Everything your Ps will see (all scales, measures)
- Training of all of your personnel
- Methods of recruiting Ps
- Weighing risks (to Ps) against benefits (to society)
- Ensuring your consent form is appropriate
- Ensuring your debriefing process is sufficient

Informed Consent

Potential participants in a research project should be provided with information that might influence their active decision to participate

<u>information, comprehension, voluntariness:</u>

- Ps know what tasks they are agreeing to do.
  - including anticipated risks & benefits
- Ps know their rights.
  - given sufficient time, help to understand
- Ps are not coerced.
  - can decline to participate without penalty
  - can stop participating at any time without penalty
  - compensation is fair but not so high as to be coercive

Informed Consent

Informed consent form covers:

- Purpose of the research
- Procedures that will be used
- Risks, benefits, and compensation
- Confidentiality
- Assurance of voluntary participation and permission to withdraw
- Contact information for questions

Debriefing

Occurs after completion of the study

Meant to ensure participants leave the experiment without any ill feelings toward the field of psychology

Aims of debriefing:

- To provide a rationale for what occurred during the study, the purpose of the study and anticipated results.
- Opportunity for the researcher to deal with issues, and harmful effects of participation
- Provides additional resources

Important cases

Vulnerable populations

Persons who are relatively (or absolutely) incapable of protecting their own interests.

- Children
- Pregnant women, fetuses, and neonates of uncertain viability
- Prisoners
- Active duty military service members
- Adults with diminished capacity

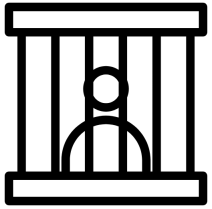
Vulnerable populations: Children

Can a child give informed consent?

- Infants & young children are considered unable to adequately understand a study's risks & benefits.
- We give children "the opportunity to choose, to the extent they are able, whether or not to participate in research."
- Researchers must respect a child's objections to performing any task.
- A parent/guardian signs the consent form on the child's behalf.

assent rather than consent

Vulnerable populations: Prisoners



Can an incarcerated participant give informed consent?

- “On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research.”
- “On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer.”

What protections could you put in place to allow people to choose to participate in research while incarcerated,
without feeling coerced?

Withholding and Deception

Withholding some information from participants is acceptable when it does not affect decisions to participate

- Must be revealed during debriefing

Actively misrepresenting information about the nature of a study is deception

- Elaborately deceptive research was more common in the past
  - “fellow participant” is really a confederate
  - “personality assessment” is fabricated, not actually about the P at all
  - P given a placebo pill, but told it will have an effect
- Must also be revealed during debriefing

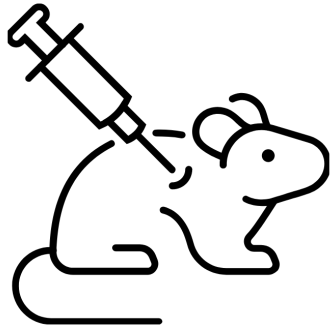
Research with non-human Animal Subjects

Animals cannot give informed consent. How do we decide what procedures are acceptable to subject them to?

American Psychological Association guidelines:

- “reasonable efforts to minimize discomfort”
- train all researchers in care & handling of animals
- only perform procedures necessary for the research
- minimize pain, infection when surgery is called for

Animal welfare is important for ethical reasons,
but also for practical one: to ensure validity and reproducibility!



Research with non-human Animal Subjects

Laws and ethical guidelines require that animals involved in research be cared for properly and prohibit cruel treatment.

Institutions engaged in animal research must have an Institutional Animal Care and Use Committee (IACUC).

- Composed of minimum one scientist, one veterinarian, and a community member
- Charged with reviewing animal research procedures and ensuring that all adhere to regulations

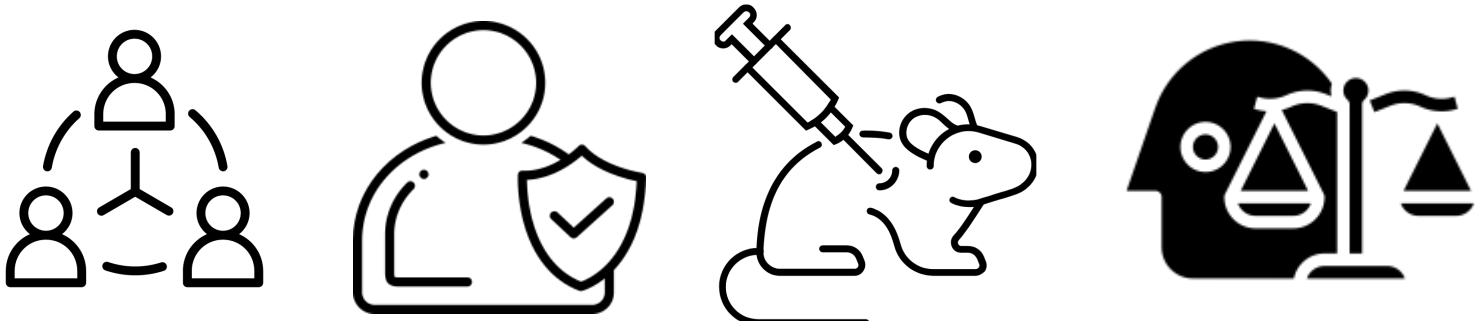
Looking beyond obligations

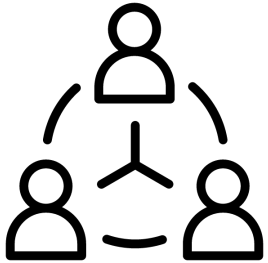
The Researcher's Own Ethics

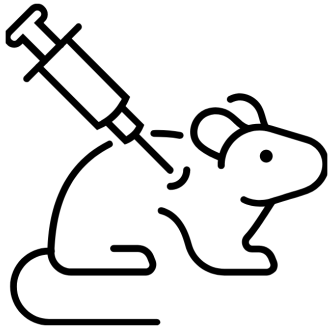
- The ultimate responsibility lies with the investigator!
- Scientists make decisions about the ethics of their research, too

Scientists must carefully consider the costs and benefits beyond what the IRB requires them to do.

Scientific community also has obligation to the communities they speak on behalf of and the larger society for which they conduct research







Ethical Scenarios Discussion

References

Slides and content were adapted from:

- SIPPS 2021 Research Ethics workshop by Cat Bianco
- HowTos of Research course by Dr. Lila Davachi, Ana DiGiovanni, and Anna Vannucci
- Research Methods: Cognition and Decision making (UN1490) course by Dr. Katherine Fox-Glassman

Other references:

- Belmont Report
- Declaration of Helsinki
- Article about Henrietta Lacks
- Ethics in Scientific Research, Weinbaum et al., 2018