# Ethics in Research

Spring 2025

Bhaktee, Vinoo, Priyanka

## Assessment:

**1.In-Class Assignments (30%)**
**2.Quiz (30%)**
**3.Final Exam (40%)**

## Grading

>90% A
>82 % A-
>74% B
>66% B-
>58% C
>50% C-
>40% D
<40% F

# What does ethics in research mean to you?

Integrity

Objectivity

Respect for others

Informed Consent

Confidentiality

Honesty

Anonymity

Right to withdraw

Respect for resources

https://www.purdue.edu/research/dimensions/important-considerations-for-protecting-human-research-participants/

# WHAT IS THE DIFFERENCE BETWEEN PRIVACY, CONFIDENTIALITY AND ANONYMITY?

Protecting research participants includes considerations for protecting their privacy, keeping information confidential, and/or allowing the participant to remain anonymous

## PRIVACY

Privacy in research refers to protecting the individual's right to control access to their participation in a study (i.e., extent, timing, circumstances).

- Carefully consider the appropriate circumstances and setting for participant recruitment, enrollment, and data collection.
- Limit the information collected to what is essential for research purposes.

## CONFIDENTIALITY

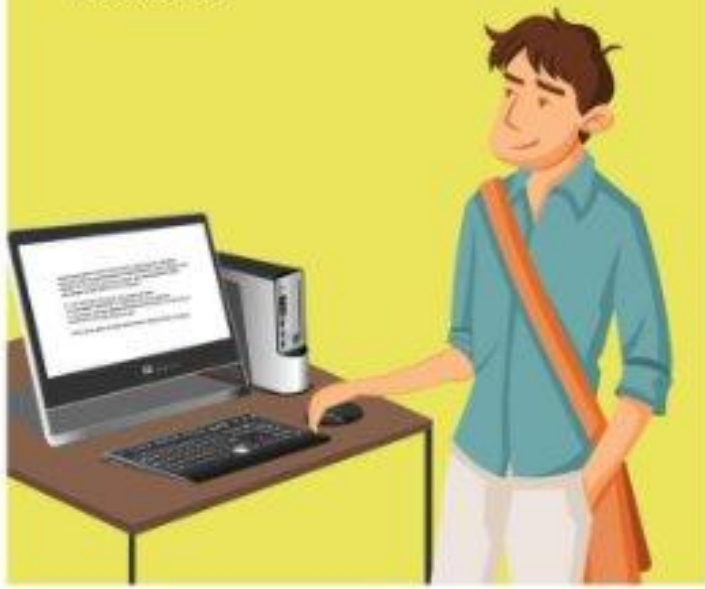
Confidentiality pertains to protecting the participant's personally identifiable data.

- Ensure that the participant's identity, personal information, responses, etc. will not be disclosed to anyone outside of the research team unless otherwise agreed upon
- Notify participants:
  - how their information will be stored during and after the study.
  - that breach of confidentiality is a potential risk of participating.
  - the steps researchers will take to secure and protect their records.

## ANONYMITY

Anonymity is protected when the researcher refrains from collecting any personal identifiers, direct or indirect, that would link responses to a specific individual.

- Data is not collected in person.
- No key codes exist, and names and other identifiers are not collected.



Each of these practices must be articulated in an IRB protocol application

- (Neural networks) https://www.adalovelaceinstitute.org/resource/research-ethics-case-studies/

- https://ki.se/en/about-ki/ethics-at-ki/case-archive/research-ethics-cases

# Clinical studies

# Ethics in Research

RULE–UNIVERSALITY

"It is possible to develop rigid codes of ethics that can be applied without exception to all psychological research."

"Lying to participants about the nature of a study is always wrong, irrespective of the type of study or the amount of information to be gained."

"What is ethical varies from one situation and society to another."

"The application of a particular code of ethics depends entirely upon the particular study; what is appropriate in one study might be totally inappropriate in another."

"Rigidly codifying an ethical position that prevents certain types of research could stand in the way of scientific advancement and prevent the accumulation of knowledge."

JOURNAL OF EXPERIMENTAL SOCIAL PSYCHOLOGY 13, 369–396 (1977)

# Tuskegee Study

https://www.youtube.com/watch?v=afwK2CVpc9E&ab_channel=BlackHistoryinTwoMinutesorso

# Ethics: The Tuskegee Syphilis Study (1932 – 1972)

Bacterial infection that is sexually transmitted

600 low-income, African-American males, 400 of whom were infected with syphilis, were monitored for 40 years. Free medical examinations were conducted; however, **the subjects were not told about their disease**. Even though a proven cure (penicillin) became available in the 1950s, the study continued until 1972, with **participants being denied treatment**. In some cases, when the subjects were diagnosed as having syphilis by other physicians, researchers intervened to prevent treatment. The study sparked off a wide-scale public outrage when it became publicly known, and the US government had to close it in 1973.

Due to the publicity from the Tuskegee Syphilis Study, a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed in the US, which was in charge of identifying the basic ethical principles that should underline the conduct of biomedical and behavioral research involving human subjects and to develop guidelines that should be followed, to assure that such research is conducted in accordance with those principles. The Commission drafted the Belmont Report, a foundational document for the ethics of human subjects' research in the United States.

**Take home message: You cannot deny treatment for the sake of research when a medicinal cure is available**

Mondal, Acharya, & Parija (2011) Tropical Parasitology

# Ethics: The Nuremberg Code (1948)

A well-known chapter in the history of research with human subjects opened on December 9, 1946, when an American military tribunal opened criminal proceedings against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. Among the charges were that German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. Most of the subjects of these experiments died or were permanently crippled as a result.

- As a direct result of the trial, the Nuremberg Code was established in 1948, stating that 'The voluntary consent of the human subject is absolutely essential,' making it clear that subjects should give consent and that the benefits of the research must outweigh the risks.

- Although it did not carry the force of law, the Nuremberg Code was the first international document, which advocated voluntary participation and informed consent.

Mondal, Acharya, & Parija (2011) Tropical Parasitology

# The Declaration of Helsinki

In 1964, the World Medical Association established recommendations guiding medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for research. The Declaration of Helsinki is the basis for Good Clinical Practices used today in research.

Issues addressed in the declaration of Helsinki include:

- Research with humans should be based on the results from laboratory and animal experimentation
- Research protocols should be reviewed by an independent committee prior to initiation
- Informed consent from research participants is necessary
- Research should be conducted by medically / scientifically qualified individuals
- Risks should not exceed benefits

Mondal, Acharya, & Parija (2011) Tropical Parasitology

# Ethics: The Belmont Report (1976)

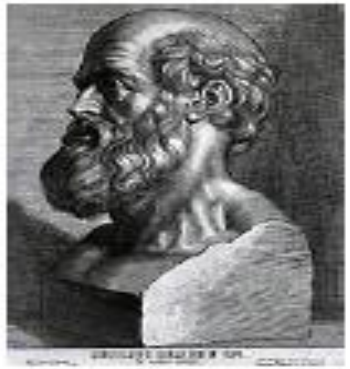
## 1. Respect for Persons

### Informed Consent

- Obtain and document
- Voluntariness/ no coercion
- Protect privacy

**IRB**

## 2. Beneficence



### Risks/Benefits

- Procedures w/least risk
- Risks reasonable in relation to benefits
- Maintain confidentiality

**Researcher**

## 3. Justice

### Enrollment

- Select participants equitably
- Avoid exploitation of vulnerable populations

**Subject**

# Institutional Ethics Committee (IEC)
# OR
# Institutional Review Board (IRB)

The role of the IRB is to protect the rights and welfare of individual research subjects. This goal is accomplished by having the IRB assure that the following requirements are satisfied:

1. risk to subjects are minimized
2. risk to subjects are reasonable in relation to anticipated benefits,
3. selection of subjects is equitable, i.e. fair
4. informed consent is sought form each subject or his/her legally authorized representative,
5. informed consent is appropriately documented,
6. when appropriate, the research plan makes provisions for monitoring data collection,
7. privacy and confidentiality of research subjects is appropriately protected, and
8. when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included.

The IRB has to approve that these requirements are followed before they approve a research study and must review these documents on, at the least, an annual basis.

# Example of Lack of Integrity

*The suggestion that MMR vaccine might lead to autism had its origins in gastroenterology research by Andrew Wakefield in the United Kingdom. In 1998, Wakefield and colleagues published an article in* The Lancet *claiming that the measles vaccine virus in MMR caused inflammatory bowel disease, allowing harmful proteins to enter the bloodstream and damage the brain.*

*The validity of this finding was later called into question when it could not be reproduced by other researchers. In addition, the findings were further discredited when an investigation found that Wakefield did not disclose he was being funded for his research by lawyers seeking evidence to use against vaccine manufacturers. As a result, Wakefield was permanently barred from practicing medicine in the United Kingdom and* The Lancet *retracted the original article in 2010.*

*There is no scientific evidence that MMR vaccine causes autism. The question about a possible link between MMR vaccine and autism has been extensively reviewed by independent groups of experts in the United States, including the National Academy of Sciences' Institute of Medicine (now renamed the National Academy of Medicine). These reviews have concluded that the available epidemiologic evidence does not support a causal link between MMR vaccine and autism.*

*evidence showed that Wakefield and his team were highly selective in choosing children for their study. They had altered the children's medical histories, and had received funding for the research from a law firm representing parents who were suing the makers of the MMR vaccines*

*However, the harm was already done. Lancet is considered a trustworthy journal. People began to stop vaccinating their children which lead to an increase in the cases of measles in the US in 2008. Misconceptions based on fraudulent research make their way into the mainstream of culture and are difficult to root out*

**Take home message: Fraudulent research (Lack of Integrity) can affect people's lives**

# What Constitutes Misconduct in Research?

Three categories of research misconduct:

1. Data fabrication: Making up data or results and recording or reporting on them.

2. Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

3. Plagiarism: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

# Clinical Trials

- For patients with terminal illness?
- When can placebo condition be used in clinical trials?

# Case Study

**Using AI to Analyze Data (Case #3)**

Dr. Falcon, a postdoc in Dr. Hawk's research group, has struggled to analyze health survey and genomic data from a longitudinal NIH intramural research study with 10,000 human participants. Dr. Falcon wonders if they might be able to use artificial intelligence (AI) tools to help analyze the data. Dr. Falcon has an account for an NIH ChatGPT platform, but this version of ChatGPT does not have the functionality needed for this data analysis, so they sign up for a personal account with a commercial AI platform, HotBot1, which is able to analyze data from publicly accessible health databases that is similar to the IRP study data. Dr. Falcon uses HotBot1 to search for statistical relationships among dozens of variables from the public databases; however, Dr. Falcon soon realizes that to make significant progress, they need to supplement the publicly available data with additional, more detailed data. Fortunately, the IRP study includes the data needed to improve the analysis and HotBot1 allows users to upload data to the platform.

Dr. Falcon de-identifies the intramural study data so it includes no names or personal identifiers and uploads them to HotBot1. After several weeks of work, Dr. Falcon has some promising results, including a genetic association that could have important public health implications. Although the analysis appears to misrepresent findings for an underrepresented minority cohort of the data, Dr. Falcon is confident that the rest of the analysis is completely reliable. Dr. Falcon shares the results of this work with Dr. Hawk at their next regularly scheduled meeting and tells Dr. Hawk how HotBot1 was used to analyze both the public and intramural datasets together. While Dr. Hawk is not very familiar with AI tools, Dr. Hawk is excited about the new findings. They quickly draft a manuscript reporting the results of their data analysis and submit it for publication clearance review in their IC.

1. Has Dr. Falcon done anything wrong? If so, what actions should be taken to mitigate any mistakes?

2. Were the steps that Dr. Falcon took to protect NIH data sufficient? Has Dr. Falcon committed a data breach incident that should be reported?

3. How can scientists balance the need to develop their research program quickly with their lack of formal education in emerging technologies?

4. How could HotBot1 have made an error in analyzing the underrepresented minority cohort of the population? What are the implications of using the entire dataset despite the concerns? How could this problem have been anticipated or prevented?

5. In your opinion, is Dr. Hawk appropriately overseeing the research of Dr. Falcon? Should Dr. Hawk have been informed by Dr. Falcon that they were embarking on this exploratory path? Should Dr. Hawk delve more deeply into the work that Dr. Falcon did using HotBot1, or is it acceptable for Dr. Hawk to trust Dr. Falcon without independently verifying any of the analyses?