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terms
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time
dimension
mean
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independent
decide
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philosophical
behaviour
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place
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CONTENTS

- What is Research Ethics?
- Issues in Research Ethics
- Responsible Conduct of Research
 - Research Misconduct
 - Conflict of Interest

DEFINITION OF RESEARCH ETHICS

- Research ethics are *a set of principles or guidelines* that will assist the researcher in making difficult research decisions and in deciding which goals are most important in reconciling conflicting values.

WHAT IS RESEARCH ETHICS?

- **Research ethics** is specifically interested in the **analysis of ethical issues** that are raised when people are involved as participants in research.
- There are 3 objectives in research ethics:
 1. To **protect** human participants;
 2. To ensure that research is conducted in such a way that **serves interests** of individuals, groups and/or society as a whole;
 3. To examine specific research activities and projects for their **ethical soundness**, looking at issues such as the management of risk, protection of confidentiality and the process of informed consent.

WHAT IS RESEARCH ETHICS?

- Research ethics has traditionally focused on **issues in biomedical research** which has influenced much of existing statutes and guidelines for the ethical conduct of research.
- In humanities and social science research, different kinds of ethical issues arise.
- **New and emerging methods** of conducting research raise important but markedly different ethical issues and obligations for researchers.
- Research involving **vulnerable persons**, which may include children, persons with disabilities, persons who are homeless or without legal status also raises unique issues in any research context.
- Research ethics everywhere today are challenged by issues that reflect **global concerns** in other domains, such as the conduct of research in developing countries, the limits of **research involving genetic materials**, and the **protection of privacy** in light of advances in technology and Internet capabilities.

VALUES AND ETHICS

- **Ethical standards** are necessary to resolution of values conflicts:
 - Value of research to society and to researcher
 - Value of personal freedom and safety to research subjects
 - Value of human life, suffering, and comfort vs. non-human animals life, suffering and comfort.
- **Value conflicts** encountered in social work research:
 - Informed consent
 - Privacy
 - Mental distress due to research
 - Protection of vulnerable clients
 - Honest disclosure of results
 - Withholding treatment to provide experimental control.

A LITTLE HISTORY

- It is important to look at history
 - We learn from our mistakes
 - History can repeat itself!
- The Nuremberg Doctors Trial of 1946
- The ‘Milgram Study’
- Untreated Syphilis Study

THE NUREMBERG DOCTORS TRIAL OF 1946

- Due to medical experiments many people died
 - The German Air Force
- High altitude experiment
 - 40% of the 200 participants died
- Parachuting into cold water experiment
 - 300 prisoner-participants suffered a mortality rate of 30%
- Wound, burns, amputation, chemical and biological agent exposure experiment
 - many died or were ruined for life
- Many experiments went on throughout the WWII
 - A mortality rate of 25% was typical

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5719716/>



THE 'MILGRAM STUDY'

OBEDIENCE TO AUTHORITY

- This study involved administering electric shocks up to extreme levels
- **Deception** was used causing some psychological stress
- **Informed consent** was not obtained
- Federal guidelines now instruct IRBs and investigators to:
 - consider not only physical harms, but also psychological, social, legal, and economic.

‘MILGRAM EXPERIMENT’

“ I observed a mature and initially poised businessman enter the lab smiling and confident.

Within 20 minutes he was reduced to a twitching, stuttering wreck, who was rapidly approaching a point of nervous collapse.”

S. Milgram in *Obedience to Authority*

<https://www.simplypsychology.org/milgram.html>

<https://www.youtube.com/watch?v=yr5cjyokVUs>

UNTREATED SYPHILIS STUDY

- Known as the Tuskegee Study
- The control group was denied the penicillin treatment even though it was widely available
- Study is striking example of many things including:
 - Lack of informed consent
 - Lack of follow up and record keeping
 - Lack of Beneficence and Respect for Persons
 - Deception and coercion
 - Lack of effective oversight
 - Targeting a vulnerable population
 - Withholding effective treatment

- “Sometimes, with the best of intentions, scientists and public officials and others involved in working for the benefit of us all, forget that people are people. They concentrate so totally on plans and programs, experiments, statistics – on abstractions – that people become objects, symbols on paper, figures in a mathematical formula or impersonal ‘subjects’ in a scientific study.”

From an article in the Atlanta Constitution on July 27, 1972 reacting to the revelations concerning the Syphilis Study.

<https://www.cdc.gov/tuskegee/timeline.htm>

THE BELMONT REPORT

- The cornerstone statement of **ethical principles** upon which the federal regulations for the protection of participants are based.
- *The basic ethical principles:*
 - **Respect for Persons**
 - individuals should be treated as autonomous agents
 - persons with diminished autonomy are entitled to increases protection
 - **Beneficence**
 - persons are treated in an ethical manner by respecting their decisions and protecting them from harm
 - maximize possible benefits and minimize risks
 - **Justice**
 - fairness in distribution

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

RESPECT FOR PERSONS

- This principle is captured in the **consent process**.
- We must consider different **types of participants**
 - Vulnerable participants
 - Prisoners
 - Children
 - Subordinate individuals
 - Decisionally impaired

BENEFICENCE

- Obligations of beneficence affect both individuals and society
- We must weigh the **risks** and the **benefits**.
 - Risk refers to a possibility that harm may occur
 - benefit refers to something of positive value
- Determining the balance constitutes an ethical dilemma in research
 - Even if the benefit to science and society is great, never should we forgo participant protection.

JUSTICE

- The **principle of justice** is captured in the selection process.
- Justice requires exclusion of those groups unlikely to be among beneficiaries of subsequent applications of the research.
- Justice requires inclusion of diverse populations so that they may benefit from the research findings.

ETHICAL ISSUES IN RESEARCH

- 1) Define and apply basic terms relating to the **ethical conduct of research** including research misconduct, fabrication, falsification, plagiarism, compliance, ethically prohibited behavior, ethically required behavior, ethically permitted behavior, and ethically encouraged behavior.
- 2) Distinguish between **compliance** and **ethics**.

ETHICAL ISSUES IN RESEARCH

Compliance and Ethics Terms

- **Compliance** and **ethics** are both necessary for the conduct of responsible research.
- **Compliance** means that investigators and institutions **follow the rules** that are set out for them.
- Rules regarding research come from the federal government, from funders, and from the institution itself.
- The essential elements of compliance are that an individual researcher **knows the rules** and that he or she is **motivated** to follow the rules.

ETHICAL ISSUES IN RESEARCH

- **Ethics** is the study of how human action affects other humans, sentient beings, or the ecosystem.
- Ethical researchers understand that their actions have the **potential of causing harm** and the **potential of promoting good** for others, for the profession, for society, and for the natural world.
- They are aware of the **special responsibilities** that follow from the researcher role and work to fulfill those responsibilities.
- In the process of meeting their responsibilities, they seek to **promote good** when possible. Always, at a minimum, they choose actions that **do not cause unjustified harm**.

ETHICAL ISSUES IN RESEARCH

- **Fabrication**, for example, is a type of research misconduct which is legally and ethically prohibited.
- Fabrication is the act of **making up data or results**, then recording or reporting them as part of the research record.
- It is legally required for funding agencies and research institutions to take punitive actions against researchers who fabricate. They are **held accountable** for their actions.

ETHICAL ISSUES IN RESEARCH

Research: includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics.

- This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and all research involving human subjects or animals, regardless of originating discipline.
- **Research**, according to the *Belmont Report*, is an "activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalized knowledge (expressed, for example, in theories, principles, and statements of relationships)".

ETHICAL ISSUES IN RESEARCH

- Research is usually described in a formal protocol that sets forth **an objective** and a **set of procedures** designed to reach that objective.
- **Research Record:** The **record of data or results** that embody the facts resulting from scientific inquiry and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

ETHICAL ISSUES IN RESEARCH

- **Research Misconduct:** Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- *It does not include honest error or honest differences in interpretations or judgments of data.*
 - **Fabrication:** Making up data or results and recording or reporting them as factual results.
 - **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.

ETHICAL ISSUES IN RESEARCH

- **Plagiarism:** The appropriation of another person's **ideas, processes, results, or words** without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts.

ETHICAL ISSUES IN RESEARCH

Findings of Research Misconduct:

- A finding that research misconduct, in fact, occurred requires that the fabrication, falsification, or plagiarism be **a significant departure from accepted practices** of the relevant research community; and the misconduct be **committed intentionally, knowingly, or recklessly**; and the allegation be proven by a preponderance of evidence.

ETHICAL ISSUES IN RESEARCH

- The questions relating to **ethics in research** are a **subset** of the questions that relate to **general morality**.
- **General morality** dictates that it is not acceptable to cause pain, death, disability, or deprive someone of freedom or pleasure without justification.
- General morality also requires that acts of deception, cheating, promise-breaking, law-breaking and neglect of responsibility be considered **examples of wrongdoing** unless there is justification for the acts.

ETHICAL ISSUES IN RESEARCH

- **Justification:** Ethically acceptable exceptions to doing what is usually expected have the following features:
 - 1) If they are **justified for any person**, they are **justified for every person** when all of the ethically relevant features are the same (one cannot justifiably make an exception of oneself if one is not willing to make the same exception for everyone in the same situation);
 - 2) The exception **cannot** cause unjustified harm to oneself or others; and
 - 3) The exception can be **known publicly**.

ETHICAL ISSUES IN RESEARCH

Ethical Rules

- Rules that identify **ethically questionable actions** that are known to cause suffering or cause an increased risk of causing harm.
- One set of rules is that it is **ethically prohibited** to cause pain, death, disability or deprive others of opportunity or pleasure without justification.
- Another set of rules is that it is also **ethically prohibited** to do any of the following **without good reason**: deceive, cheat, break promises, break the law, or neglect one's duty.

ETHICAL ISSUES IN RESEARCH

Ethical Ideals

- Ideals are **actions that lessen** the amount of harm suffered or **decrease** the risk that people, other sentient beings, or the ecosystem will suffer harm.
- As long as one is not violating an ethical rule, general morality **encourages, but does not require**, following ethical ideals.
- People are **praiseworthy** for following ethical ideals, but are **not blameworthy** for not performing the ideal.

ETHICAL ISSUES IN RESEARCH

- **Ethically Prohibited:** Actions that are **contrary to** those required by general morality or by reasonable expectations within the research community and are not justifiable.
- People are **blameworthy** for acting in ethically prohibited ways. By way of example, it is ethically prohibited to violate the **rules and regulations** regarding responsible research that are set out by the federal government, funders, and research institutions.
- **Ethically Permitted:** Actions that are **consistent** with those required by general morality and by reasonable expectations within the research community. It is ethically permitted to do **more than** follow minimal rules and regulations.

ETHICAL ISSUES IN RESEARCH

- **Ethically Required:** Actions that follow from the special role-related responsibilities of being a researcher. It is ethically required that researchers be **in compliance with federal and institutional rules and regulations.**
- **Ethically Encouraged:** Actions that are **ethically permitted** and, in addition, are intended to lessen suffering or lessen the risk of suffering harms.

GUIDELINES ON ETHICS

- UNIMAS subscribes to the governing principles of the UK-based Committee of Standards in Public Life
- UNIMAS Animal Ethics
- Malaysian Good Clinical Practice Guidelines
- International Committee on Harmonisation Guidelines on Good Clinical Practice in Clinical Trials
- Medical Research and Ethics Committee

Setting off on the road to the responsible conduct of research



When research misconduct becomes public



CONFLICT OF INTEREST

- A **conflict of interest** is a situation in which financial or other personal considerations have the potential to **compromise or bias** professional judgment and objectivity.
- An **apparent conflict of interest** is one in which a reasonable person would think that the **professionals judgment** is likely to be compromised.
- A **potential conflict of interest** involves a situation that may develop into an actual conflict of interest.
- A conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the **potential for bias**, not a likelihood.



"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."

CONFLICT OF INTEREST

- There are many varieties of conflicts of interest, and they appear in different settings and across all disciplines.
- While conflicts of interest apply to a "wide range of behaviors and circumstances," they all involve the use of a person's authority for personal and/or financial gain.
- Conflicts of interest may involve individuals as well as institutions.
- Conflicts of interest are broadly divided into two categories:
 - **Intangible** - those involving academic activities and scholarship;
 - **Tangible** - those involving financial relationships.

ACADEMIC CONFLICTS OF INTEREST OR INTELLECTUAL BIAS

- An **academic conflict of interest** could occur if an individual interferes with the **peer-review process** for some type of intangible personal gain.
- **For example, bias** can cause a reviewer to respond positively to a manuscript because it presents results favoring a method or production in which **the reviewer has a personal interest**, or a reviewer may act **to delay the publication** of a competitor's manuscript in order to strengthen his or her own chances for publication or funding.

