Ethics of Scientific Research
أخلاقيات البحث العلمي

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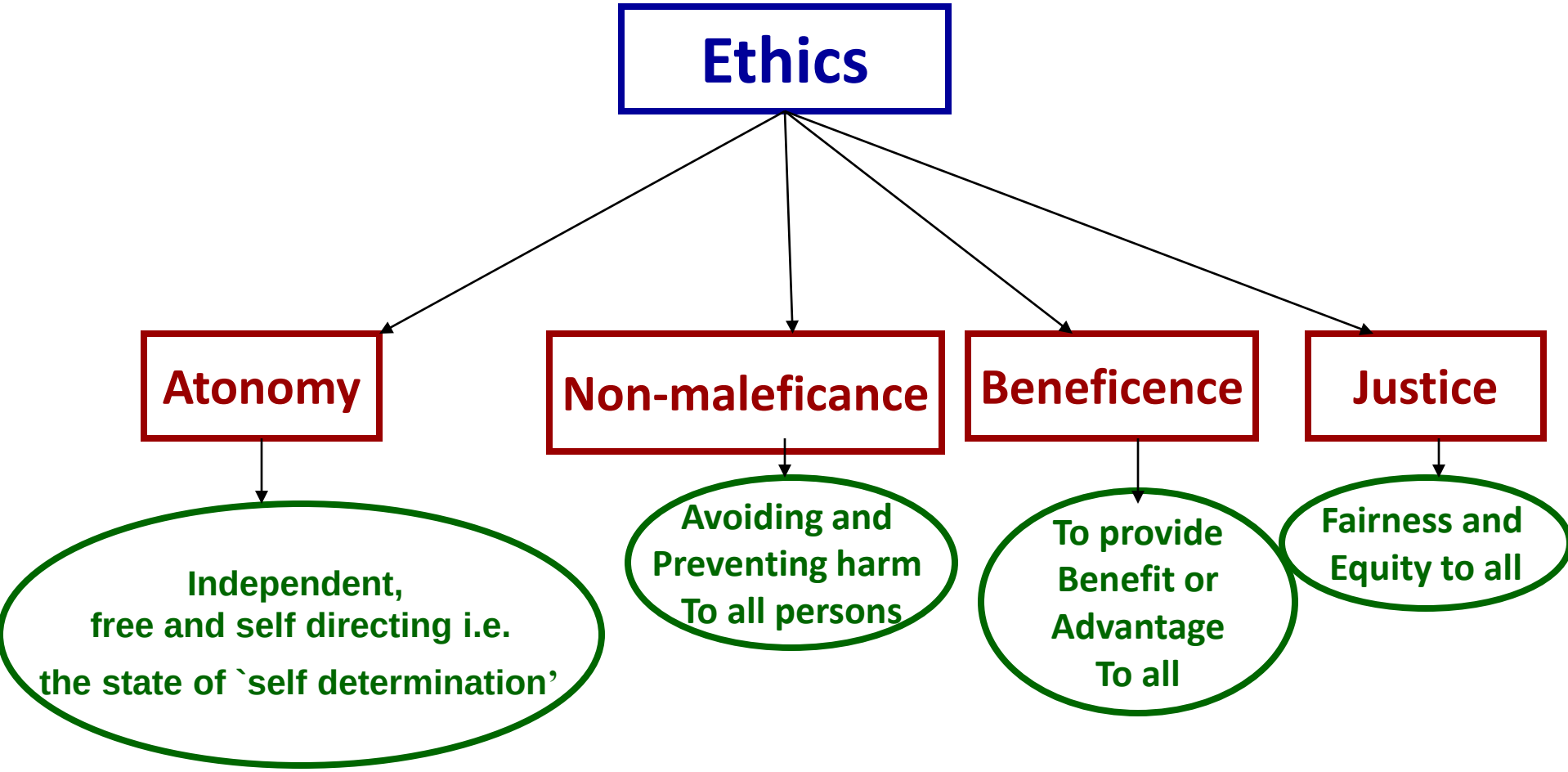
Ethics

- **Ethics (**moral philosophy)**:** The study of the general nature of morals (اخلاق) and of the specific moral choices to be made by a person (Norms for conduct that distinguish between acceptable and unacceptable behavior).
- The term comes from the Greek word ethos, which means "character".
- Ethics seeks to resolve questions dealing with human morality—concepts such as:
  - good and evil,
  - right and wrong,
  - virtue and vice
- **Ethical:** in accordance with the accepted principles of right and wrong that govern the conduct.

Basic principles of Ethics



Research Ethics

- **Research ethics** involves the application of fundamental ethical principles to research.
- Research ethics is most developed as a concept in medical research, but in some form is essential for all research.
- Medical and biological research ethics includes the design and implementation of research involving :
  - human experimentation,
  - animal experimentation,
  - various aspects of academic scandals including scientific misconduct (such as fraud, fabrication of data and plagiarism), regulation of research, etc.
- Research in the social sciences presents a different set of issues than those in medical research.
  - various aspects of academic scandals including scientific misconduct (such as fraud, fabrication of data and plagiarism), regulation of research, etc.

Historical Background-
The Basics of Ethics in Research

- A little over50-60 years there were no research ethics essentials for researchers to follow and they could do whatever they wanted.
- Dishonest, fraudulent, or unethical researchers were carried out
- Notable examples:

Human Research Abuses

1. German Nazi Experimentation

   Prisoners were forced into participating; they did not willingly volunteer and there was never informed consent..

   – Freezing Experiments
   – Malaria Experiments
   – High-Altitude Experiments
   – Head injury experiments
   – Mustard gas experiments

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- Typically, the experiments resulted in death, disfigurement or permanent disability, and as such are considered as examples of medical tortures.
- On 19 August 1947, the doctors captured by Allied forces were put on trial in *USA vs. Karl Brandt et al.*, which is commonly known as the Doctors' Trial.
- At the trial, several of the doctors argued in their defense that there was no international law regarding medical experimentation.
- Charges brought against 23 German physicians in the Nuremberg War Crime Trials for their medical experiments
- Led to the development of Nuremberg Code (1948)

Nuremberg Code (1948)

1. The voluntary consent of the human subject is absolutely essential.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disability injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Thalidomide Tragedy

- Thalidomide was used in the late 50's and early 60's to alleviate morning sickness in pregnant women.
- The drug interfered with the babies' normal development, causing many of them to be born with phocomelia, resulting in shortened, absent, or flipper-like limbs.

Other tragedies

- 1960's
  - Human Radiation Experiments
  - Willowbrook Studies (1963-1966)-Children with developmental disabilities were deliberately infected with Hepatitis (some were even fed fecal matter). Purpose of the study was to examine the course of the disease and to test a potential immunization
  - Milgram's Obedience Study- Researchers asked participants to "Pseudo-shocking" confederates in order to examine obedience

- 1970's
  - Tuskegee Syphilis Experiment (1932-1972)-American researchers purposely withheld treatment for 399 African-American people with syphilis for the sole purpose of studying the long term effects of the disease.

  - Stanford Prison Experiment. Zimbardo's Stanford Prison Experiment (1971). Study had to be ended prematurely because of abusive behaviors generated participants who where assigned as guards over those subjects that were assigned as prisoners.

(Courtesy National Archives)

Outcome of these Unethical Researches

Establishment of several codes of action:

1. Nuremberg Code (1948).
2. NIH Ethics Committee (1964)
3. Declaration of Helsinki (1964, ’75, ’83, ’89, ’00)
4. Beecher “Ethics & Clinical Research” (1966)
5. 1973 Congressional Hearings on Quality of Heath Care and Human Experimentation.
6. National Research Act of 1974

   - Established the IRB system.

7. Belmont Report (1979)

The Belmont Report

- The Belmont Report (1979) is the major ethical statement guiding human research in the United States.
- Put forward by: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research - April 18, 1979
- Covers three main issues:
  1. Boundaries Between Practice and Research
  2. Basic Ethical Principles
  3. Applications of Principles

Regulation of Research and Protection of Research Participants

- Proponents of situational ethics argue that no general rules can be applied to all situations – each action is unique
- Belmont report – serves as a fundamental document for current federal regulations for protection of human subjects – 3 principle:
  1. Respect for Persons
  2. Beneficence
  3. Justice
- Code requires that protocols involving human subjects be reviewed by an IRB.
- Complete Belmont report:

  http://www.ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm

1-Boundaries Between Practice and Research

- Every Institution must have a Institutional review board (IRB)
- IRB must determine that the researcher and the subject (through informed consent,) distinguishes practice from experiment in both medical science and social science research

2- Basic Ethical Principles

a. Respect for Persons

- Individual autonomy (freedom to act or function independently). Protection of individuals with reduced autonomy

b. Beneficence

- Maximize benefits and minimize harms

c. Justice

- Equitable distribution of research risks and benefits

a- Respect for Persons

- Autonomy (independence), self-determination
- Respect each individual
- Treat individuals as autonomous agents
- Allow people to make choices for themselves
- Do not use people as a means to an end
- Provide extra protection to those with limited autonomy-vulnerable group
  - *Voluntary Participation*
  - *Informed Consent*
  - *Protection of Privacy & Confidentiality*
  - *Right to Withdraw without Penalty*

Vulnerable group:

- Children,
- Women
- Prisoner
- Those with limited education
- The poor
- Those with out easy access to health services
- Patients with Mental disabilities,
- People in prison
- Animals

b-Beneficence

- Acts of kindness or charity that go beyond duty
  - Physical, mental and social well-being
  - Risks reduced to a minimum
  - Protection of the participant is the most important responsibility of the researcher

- Obligations derived from beneficence
  - Do no harm
  - Prevent harm
  - Prevent evil
  - Promote good

    - *Risks are justified by the benefits*
    - *Risks are minimized*
    - *Conflicts of interest are managed to avoid bias*

c-Justice

- Equal distribution of risk and benefit- Treat people fairly
- Equitable recruitment of research participants- Eliminate bias
- Special protection for vulnerable groups
- Share burdens and benefits of research fairly
- Distinguish procedural justice from distributive justice
  - Vulnerable subjects are not targeted for convenience
  - People are not selected as subjects because of their ease of availability or compromised position
  - People who are likely to benefit are not excluded

3- Application of Principles

- Ethical and moral principles must be applied
- All principles are essential to sound ethical research
- Principles carry equal moral weight
- Ethical conduct is expected

Institutional Review Board (IRB)

- The National Research Act (law) in 1974, established the Institutional Review Board (IRB), to provide standards of conducting ethical research, and to protect human and animal subjects.
- Any research project that receives government money must demonstrate that its methods are ethical and so must get the approval of the research proposal from the IRB
- http://irb.ufl.edu/

The role of IRB

- To protect the rights and welfare of individual research subjects.
- This 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

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6. the research plan makes provisions for monitoring data collection,

7. privacy and confidentiality of research subjects are appropriately protected, and

8. when some or all of the subjects are likely to be vulnerable to 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.

IRB Levels of Risk

- The IRB categorizes the risk associated with research into
  - Exempt,
  - Minimal, and
  - Greater than Minimal

Exempt:

Experiment is without risk to the participant, the researcher, and the environment

Examples:

- Anonymous questionnaires,
- Standardized education tests, and
- Anonymous naturalistic observations

Minimal Risk:

Although safeguards must be present, usually no more risk than one would face in everyday life

Examples:

- Certain Medical Diagnostic tests,
- Research on individual or group behavior that involves no manipulation of the subjects and is not stressful (i.e., research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior), and
- Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Greater than Minimal Risk

Can cause stress, pain, injury, or even death. A project that involves greater than minimal risk requires approval by an IRB panel composed of members qualified to review research in that field.

Examples:

- Research with children and other vulnerable populations;
- Research that involves experimental drugs or devices, invasive procedures;
- and any research involving deception.

Research Ethics: Areas of Focus

a. Harm
b. Informed Consent
c. Confidentiality
d. Deception
e. Reporting Results and Plagiarism

a-Harm

- The research will not harm the participants in any way physically, psychology, socially
- Researchers should take every precaution to ensure that participants are not subjected to undue harm or stress

b-Informed Consent

- The following points must be followed:
  1. Subjects are made fully aware of the nature and purpose of the research project
  2. Consent is voluntarily given
  3. The person involved has the legal capacity to give consent
  4. The responsibility for obtaining consent rests with the researcher

* Sometimes, because of the Hawthorne Effect (the alteration of behaviour by the subjects of a study due to their awareness of being observed), it may be necessary to use some deception in telling subjects about the study.

Informed Consent

- Voluntary Informed Consent is essential for research involving human subjects
- Informed Consent should include:
  - Description of the nature of the research
  - Statement that the research is voluntary and participants can withdraw at any time
  - Identification of Risks and Benefits
  - Description of protection of confidentiality
  - Description of compensation
  - Description of what info researchers will share with participants
  - Identification of who is responsible for research with contact information

c-Privacy and Confidentiality

- Privacy refers to capacity of individuals to control when and what conditions others have access to their behaviors, beliefs, and values.
- Confidentiality refers to linking information to a person's identity
- Informed consent should indicate how researcher will protect confidentiality of participants
- Some procedures that can ensure confidentiality:
  - Obtaining anonymous information
  - Code data so that identifying info is eliminated
  - Substitute other names
  - Do not release or report individual data
  - Limit access that could reveal individual identity
  - Report data only in group form
  - Used computerized methods for encrypting data

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- All information collected in a research project should remain confidential
  - Participants should be assigned a compliant code
  - Data should be locked away in a secure setting
  - Electronic Databases should also be protected

CAN YOU THINK OF EXAMPLES WHERE CONFIDENTIALITY WOULD BE IMPORTANT?

- Name
- Genetic condition
- Diseases
- Treatment with drugs (fertility)

d-Deception

- At times, researchers may choose to hide from participants the true nature of the study
- Deception by Omission
  - Withholding important facts from the participants
- Deception by Commission
  - Lie to or purposely mislead research participants

Deception

- Staged Manipulations
  - Also called Event Manipulations
  - Used for 2 reasons
    - The researcher may need to create some sort of psychological state (anxiety)
    - The researcher may need to stage a manipulation to recreate a real-world scenario
      - Having a participant do one task and then having them do more tasks at the same time
- Staged manipulations usually employ a confederate
  - Also called an accomplice
  - A confederate is someone who appears to be another participant in an experiment but is really a part of the experiment
- Example: Someone who purposely insults a participant in a study in order to provoke anger or frustration

Deception

- Researchers can us deception under certain conditions:
  - Participants must be provided with enough information to consent voluntarily
  - Researchers must convince the IRB that deception is necessary to collect data and that it will cause little or no harm
  - Researchers must arrange to fully inform the patients of the true nature of the study in a timely manner

d-Reporting Results and Plagiarism

- Results of research studies should be reported in a honest, accurate manner
  - Researchers cannot “manipulate” data to fit their hypotheses
  - Researchers cannot make up or report false results
  - Researcher must report what they find, even if the data does not support their initial hypotheses
  - Researchers should ensure that data is being collected consistently (do checks of research assistants)
  - Researchers should give the proper credit (authorship) to those who have earned it

Data Manipulation

Researchers who manipulate their data in ways that deceive others are violating both the basic values and widely accepted professional standards of science. - failure to fulfill all three obligations.

- They mislead their colleagues and potentially impede progress in their field or research.
- They undermine their own authority and trustworthiness as researchers.

Plagiarism

- Avoid plagiarism in all research, reporting, writing
- Comes from the Latin word meaning "to kidnap"
- e.g.:
  - Copying someone else's words without proper citation
  - Copy and pasting from other manuscripts
  - Stealing someone else's ideas
  - Stealing someone else's intellectual property

  Bottom Line: Cite sources properly and minimize quotations in research reports

Plagiarism and Self-Plagiarism

- Plagiarism: using the ideas or words of another person without giving appropriate credit
- Self-Plagiarism: The copying or reuse of one's own research

  Both types of plagiarism are considered to be unacceptable practice in scientific literature

Important points to consider

- Authorship
- Ownership of data
- Consultants

Why Publish?

- **“if it wasn’t published, it wasn’t done”**

Research Misconduct

- Scientific misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

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(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is 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.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

Other Types of Ethical Violations

- Duplicate publication/submission of research findings; failure to inform the editor of related papers that the author has under consideration or “in press”
- Unrevealed conflicts of interest that could affect the interpretation of the findings
- Misrepresentation of research findings - use of selective or fraudulent data to support a hypothesis or claim

Basic Rule

- Do not invent or distort (“fudge”) data
- Do not deceive anyone
- Do not steal data or take credit for the work of others
- Give credit to those who deserve
- No plagiarism
- If there is a mistake in reported results-get it corrected
- Do not hurt your research subjects

If we abide by these rules, we will be personally contributing to the integrity of science

So Why do you think we should Teach Research Ethics?

1. -
2. -
3. -
4. -
5. -
6. -
7. -
8. -

“Other deviations" from acceptable research practices and include: Unethical

- Publishing the same paper in two different journals without telling the editors
- Submitting the same paper to different journals without telling the editors
- Not informing a collaborator of your intent to file a patent in order to make sure that you are the sole inventor
- Including a colleague as an author on a paper in return for a favor even though the colleague did not make a serious contribution to the paper
- Discussing with your colleagues confidential data from a paper that you are reviewing for a journal
- Trimming outliers from a data set without discussing your reasons in paper
- Using an inappropriate statistical technique in order to enhance the significance of your research
- Bypassing the peer review process and announcing your results through a press conference without giving peers adequate information to review your work
- Conducting a review of the literature that fails to acknowledge the contributions of other people in the field or relevant prior work
- Stretching the truth on a grant application in order to convince reviewers that your project will make a significant contribution to the field

- Failing to keep good research records
- Failing to maintain research data for a reasonable period of time
- Making significant deviations from the research protocol approved by your institution's Animal Care and Use Committee or Institutional Review Board for Human Subjects Research without telling the committee or the board
- Not reporting an adverse event in a human research experiment
- Wasting animals in research
- Exposing students and staff to biological risks in violation of your institution's biosafety rules
- Rejecting a manuscript for publication without even reading it
- Sabotaging someone's work
- Stealing supplies, books, or data
- Rigging an experiment so you know how it will turn out
- Making unauthorized copies of data, papers, or computer progr

Conclusion

- Conducting ethical research is essential
- Lessons have been learnt from past medical and social research
- Codes and Policies are in place
- Future research activities must follow the appropriate guidelines.