# Research ethics

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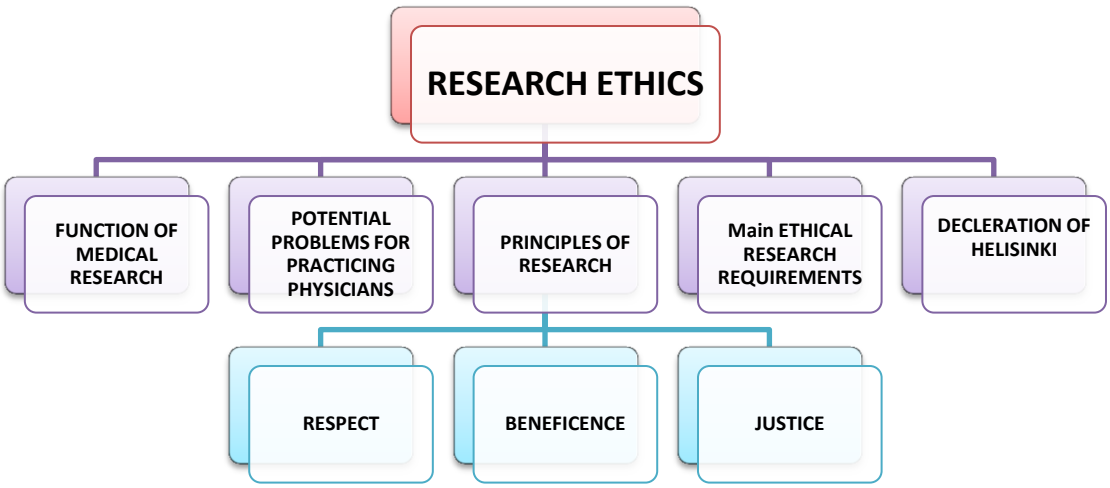
Slides | Important | Explanation

# Objectives and Mind Map

## Objectives:

1. Identify the main principles of medical research ethics.
2. Discuss the balance of research and clinical care.
3. Describe requirements of ethics review committees, including definition of informed consent.
4. Identify the key international and national references for the rules and regulations of medical research

## Mind Map:



## Main Functions of Medical Research: Important

1. Monitoring and evaluation of drugs / treatments being used.
2. Understanding human physiology .
3. Causes of diseases and the best ways to prevent or cure them.
4. The development of new treatments, especially drugs, medical devices and surgical interventions.
5. Factors in human health, including patterns of disease (epidemiology)
6. The organization, funding and delivery of healthcare (health systems research)
7. Social and cultural aspects of health (medical sociology and anthropology)

## Why do practicing physicians need a good understanding of medical research methods?

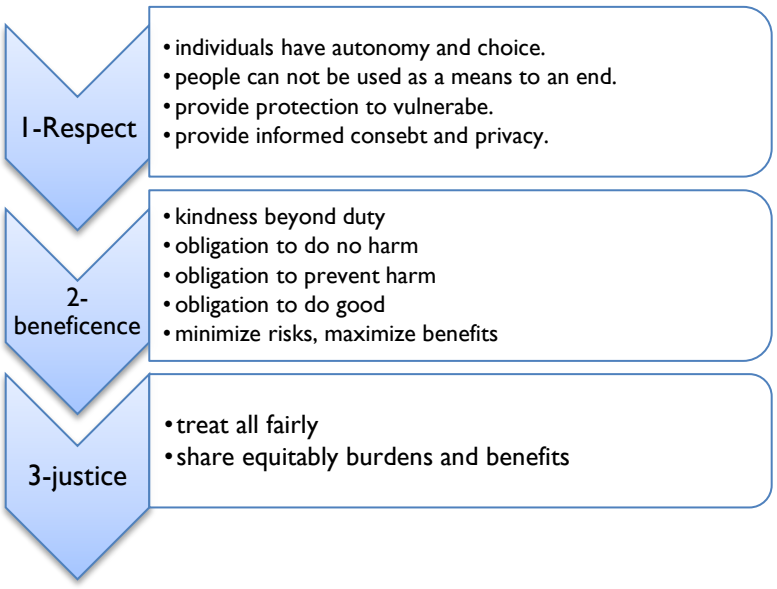
1. All physicians make use of the results of medical research in their clinical practice.
2. To maintain their competence, physicians must keep up with the current research , they must know how to interpret the results of research and apply them to their patients.

## Potential problems for practicing physicians:

1. The physician's primary responsibility is the health and well being of the patient, whereas the researcher's primary responsibility is the generation of knowledge, which may or may not contribute to the research subject's health and wellbeing.
2. Conflict of interest when the physician is influenced by financial gains from research or results of the research.

## Principles of Research with Human Subjects:

| | |
|---|---|
| 1. Respect for Persons | ١- معاملة الإنسان كشخصية مستقلة له رأيه الحر دون إكراه. |
| 2. Beneficence | ٢- الإحسان و منع الإساءة كما يجب أن لا يصيب الإنسان الضرر نتيجة للبحث. |
| 3. Justice | ٣- العدل في العبء و الفائدة المرجوة من البحث |



## Main ethical research requirements:

1. Voluntary consent
2. For good of society
3. Animal experiments 1st; human experiments 2nd
4. Avoid unnecessary suffering
5. Do not conduct if death & debility likely
6. Risk commensurate with benefits
7. Protect subjects against harm
8. Conducted only by qualified persons
9. Subjects should be at liberty to discontinue
10. Terminate if becomes apparent that death or debility will occur.

**Important**

Questions here are going to be as scenario

## Elements Should Be Included In An Informed Consent:

- **Purpose** of the research
- **Procedures** involved in the research
- **Alternatives** available should a subject decide not to participate in the research
- **All foreseeable risks and discomforts** to the subject. *Note that these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- **Benefits of the research** to society and possibly to the individual human subject
- **Length of time** the subject is expected to participate
- **Payment for participation** (if applicable)
- **Person to contact for answers** to questions or in the event of a research-related injury or emergency
- Statement that **participation** **is voluntary and that refusal to participate will not result in any consequences** or any loss of benefits that the person is otherwise entitled to receive
- **Subjects' right to confidentiality and right to withdraw** from the study at any time without any consequences.

## Declaration of Helsinki (DoH): Important

**Definition**: a concise summary of research ethics. Other, much more detailed, documents have been produced in recent years on research ethics in general.

- **Issued by**: World Medical Association

- **Important points of DoH :**

1. **Ethics Review Committee Approval:** Medical research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed.

2. **Scientific Merit:** Medical research involving human subjects must be justifiable on scientific grounds

3. **Qualified researchers :** Medical research involving human subjects must be conducted by qualified researchers.

4. **Social Value:** Medical research project should that it contributes to the wellbeing of society in general.

5. **Risks and Benefits:** It is also necessary for the researcher to demonstrate that the risks to the research subjects are not unreasonable or disproportionate to the expected benefits of the research, which may not even go to the research subjects.

6. **Informed Consent:** The first principle of the **Nuremberg Code** reads as follows: "*The voluntary consent of the human subject is absolutely essential.*

7. **Confidentiality**
   Research subjects have a right to privacy with regard to their personal health information.

8. **Conflict of Roles**
   The physician's role in the physician-patient relationship is over the researcher's role, even if the physician and the researcher are the same person.

9. **Honest Reporting of Results**
   Research results be reported accurately, but unfortunately there have been numerous recent accounts of dishonest practices in the publication of research results.

10. **Whistle-blowing**
    In order to prevent unethical research from occurring, or to expose it after the fact, anyone who has knowledge of such behavior has an obligation to disclose this information to the appropriate authorities.

11. **Justice**
    Equitable selection of participants, i.e., avoiding participant populations that may be unfairly coerced into participating, such as prisoners and institutionalized children. The principle of justice also requires equality in distribution of benefits and burdens among the population group(s) likely to benefit from the research.

# Questions

1. **Force the research's subject to do what they do not want breaks which one of medical research principles:**

A- Justice
B- Respect for persons
C- Beneficence

**2. Based on the definition of informed consent:**

**A.** The patient's permission should be granted in full knowledge of possible consequences of the medical procedure.
**B.** The patient is not required to know the possible risks and benefits.
**C.** The patient's opinion is not important.

1.B 2.A

# Quiz

- What are the main functions of medical research?
- Why do practicing physicians need a good understanding of medical research methods?
- What are the potential problems for practicing physicians?
- What are the principles of research with human subjects stated in Belmont report?
- What are the important points mentioned in Helsinki (DoH)?
- What elements should be included in an informed consent?