



(8) Ethics of Medical Research

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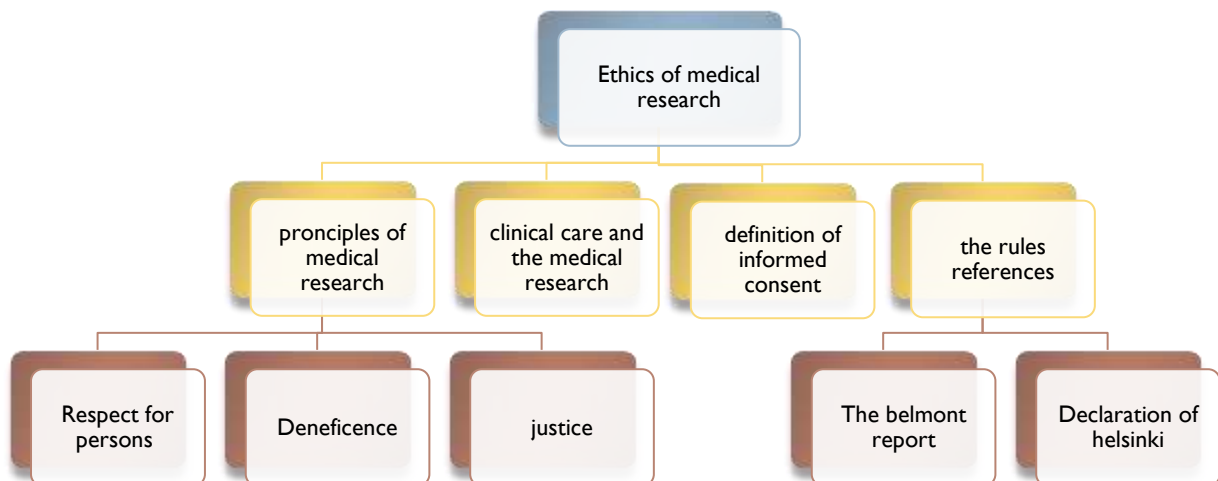
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Objectives and Mind Map

Objectives:

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

Mind Map:



Strong and Positive self-image is the best possible preparation for Success.



Ethics of Medical Research

The main principles of medical research ethics:

- **Respect for persons:** The individuals have their own choices. They can't be forced to do anything they don't want to. We should respect their privacy and provide them the protection they need.
- معاملة الإنسان كشخصية مستقلة له رأيه الحر دون إكراه.
- **Beneficence:** The harm should be prevented and minimized and the benefits should be maximized by every possible way.
- الإحسان و منع الإساءة كما يجب أن لا يصيب الضرر الإنسان نتيجة للبحث.
- **Justice:** All the individuals should be treated fairly and equally.
- العدل في العبء و الفائدة المرجوة من البحث.

Declaration of Helsinki's requirements:

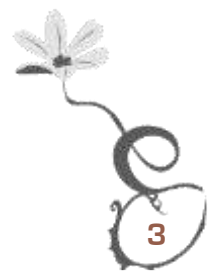
1. **Ethics review committee approval:** Medical research no human subjects must be reviewed and approved by an independent ethics committee before it can proceed.
2. **Scientific Merit:** Medical research involving human subjects must be **justifiable** on scientific grounds, **conducted** by qualified researchers (**Qualified Researchers**) and the project should **contribute** to the wellbeing of society (**Social value**).
3. **Risks and benefits:** Researchers should demonstrate that the risks to the research subjects are not unreasonable or disproportionate to the expected benefits.
4. **Informed consent:** The first principle of the **Nuremberg code** reads as follows: "the voluntary consent of the human subjects is absolutely essential".
5. **Confidentiality:** Subjects have right to privacy regarding their personal health information.
6. **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.

7. **Honest reporting of results:** Research results should be reported accurately.
8. **Whistle-blowing:** Report any information regarding an unethical research to the appropriate authorities.
9. **Justice:** Equitable selection of participants and distribution of benefits among the population.

The **Nuremberg Code** is a set of research ethics principles for human experimentation set as a result of the Subsequent Nuremberg Trials at the end of the Second World War.

Important Point:

- **Kindness beyond duty** (مصلحة المريض أولاً).
- **Informed consent** is defined as: permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits.
الموافقة بعد التبصير: إعطاء الشخص موافقته بمطلق حريته دون استغلال أو اكراه، بعد أن ادرك ما يطلب منه، وأدرك أهداف البحث واحتمالات الخطر فيه وما يترتب على مشاركته من حقوق وواجبات.
- International references for the rules and regulations of medical research: **Declaration of Helsinki (DoH)** issued by **World Medical Association (WMA)**.
- Examples:
 - Any person can withdraw from the research (Respect).
 - Research must stop if there is any harm (Beneficence).



Questions

Q1: Force the research's subjects to do what they do not want breaks which one of medical research principles?

- A- Justice
- B- Respect for persons
- C- Beneficence

Q2: 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.

Q3: Regarding declaration of Helsinki's requirements, "Confidentiality" matches which one of the following statements:

- A- Research results should be reported accurately.
- B- Medical research involving human subjects must be justifiable on scientific grounds.
- C- Subjects have right to privacy regarding their personal health information.

Q4: For each of the examples below, write the most appropriate corresponding of the three ethical principle of medical research:

Example	Principle that has been violated
A- The patients participating in a drug trial were not informed that they are participating in a study.	-----
B- A research study limited only to a poor population of patients although others would benefit from it.	-----
C- Subjects not permitted to discontinue experiment.	-----
D- In a drug trial comparing two drugs A and B, it became clear that A has serious side effects and less efficacy than B. However, the researchers continued with the study because he wanted to have a large number of cases studied.	-----



Answers:

- 1- B
- 2- A
- 3- C
- 4- Respect for persons / Justice / Respect for persons / Beneficence

