

Ethics in Medical Research: *Breaches & Legal Status*

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Ethics : Moral principles that govern a person's behaviour or the conducting of an activity.

«Medical ethics also enter into the question»

Ethics : The branch of knowledge that deals with moral principles. *«Neither metaphysics nor ethics is the home of religion..»*

Phase 3 lecture, 2023 - 24

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Learning objectives....

At the end of this lecture, students are expected to :

- Distinguish between ***Ethics*** and ***Morality***,
- Will be able to reply the basic questions of ***Ethics***,
- Recognize ***Ethics*** as a field of knowledge,
- Will be able to comprehend the importance of ***Ethics***.
- In particular, will meet with ***Public Health Ethics***;
- Will be able to acquire key ethical principles in the **research** of Health / Public Health services and sciences.



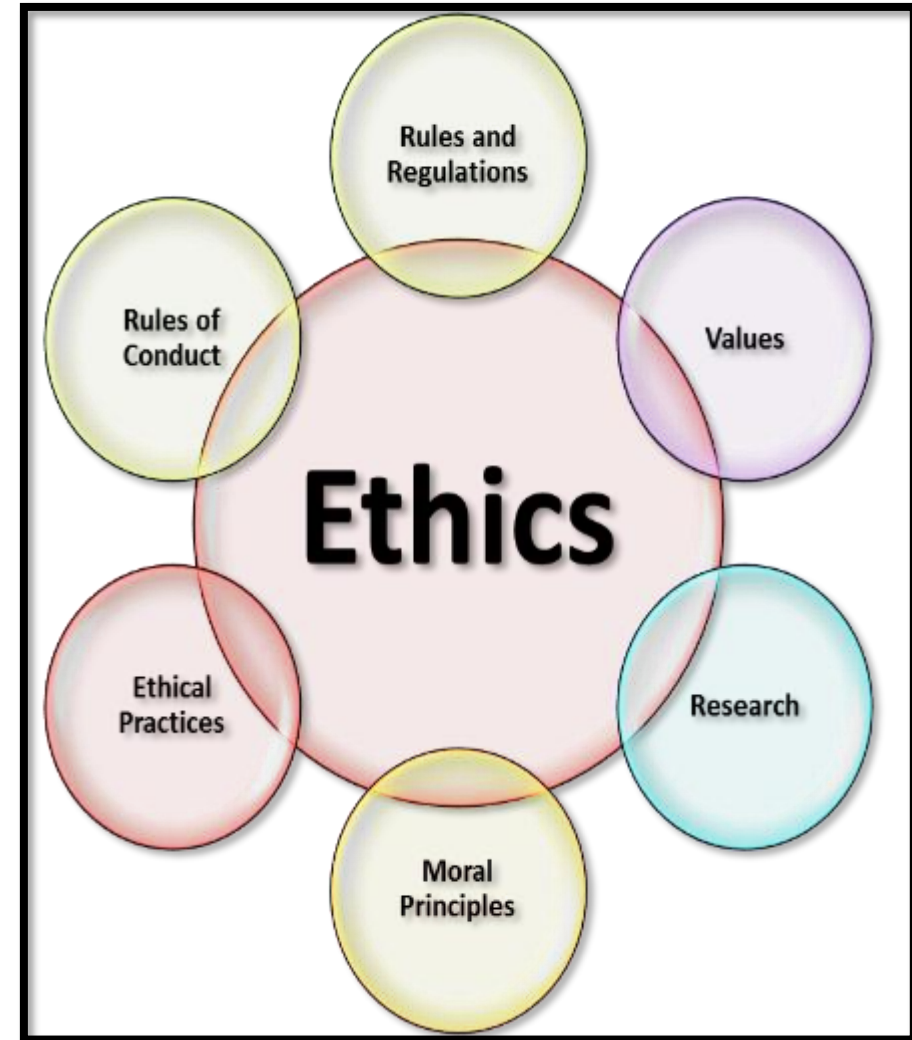


If you were to choose your name and surname among these words, which ones would you take / would you not take, and why??

- **"Morality"**; Social order rules that regulate the behavior patterns that people have to obey in a society.
- **Ethics**; It is all of the moral principles that are the basis of one's behavior. In other words, *Ethical people*; they are guiding values, principles and standards that help determine *"how things should be done."*

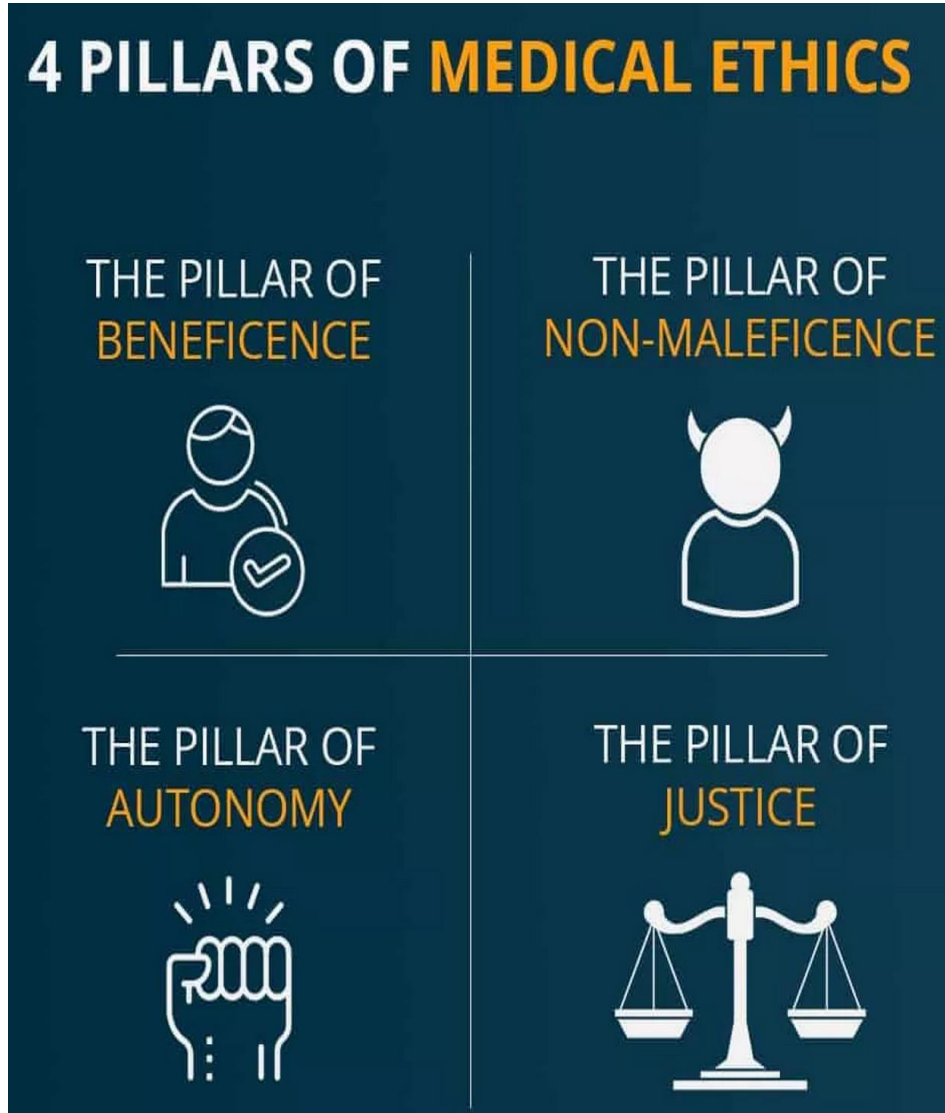
Origin & Meaning of the Word Ethics-1

- The word **Ethics** comes from the ancient Greek word (*Ethos*). The origin of this word is the word (*Ethika*).
- The word «**Ethika**» here means "issues related to the ethe", which is the plural of Ethos.

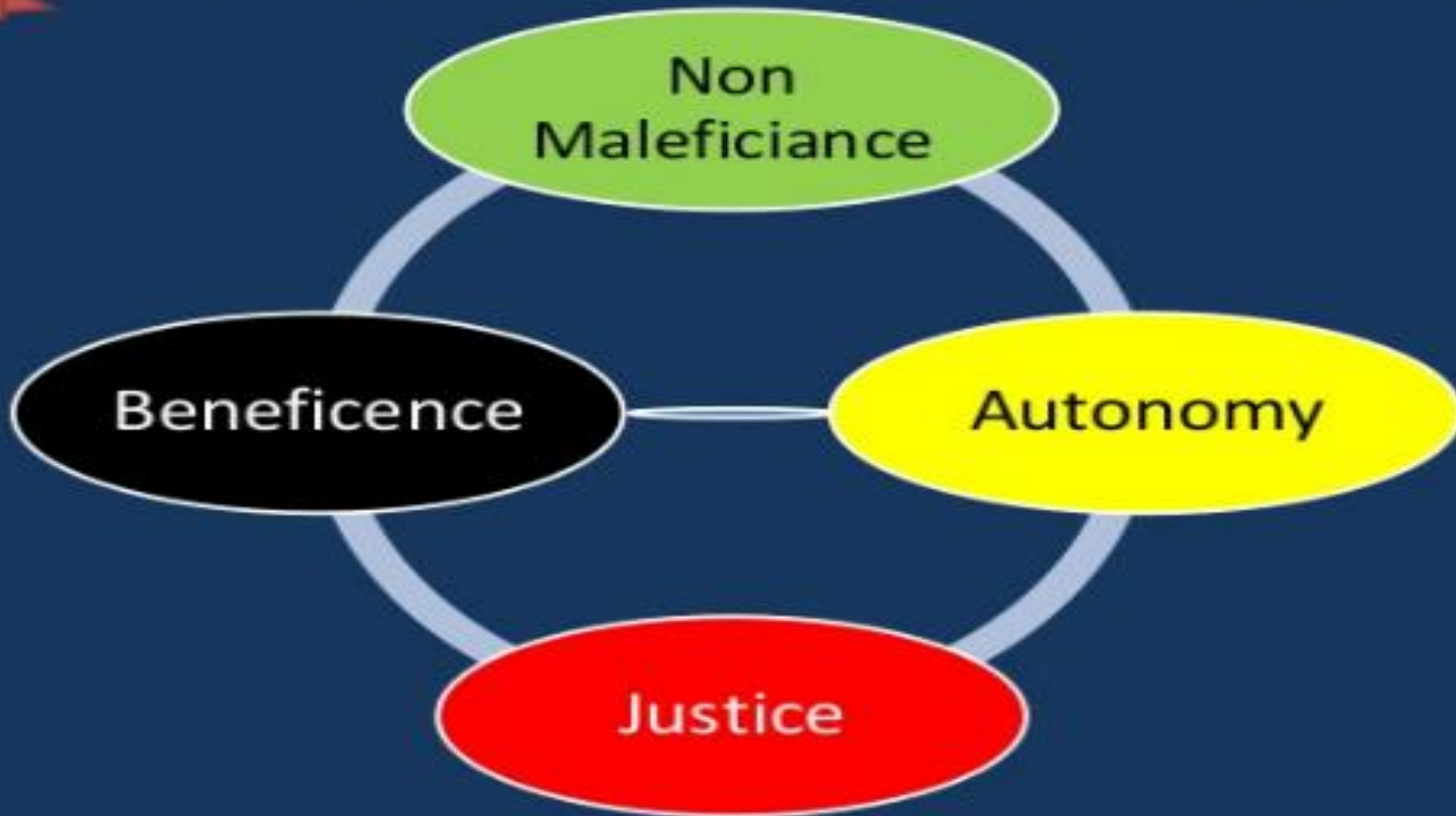


Origin & Meaning of the Word Ethics-2

- The plural of Ethos, (*Ethe*), if it is said in its oldest sense, means "the 'space' of a living being, 'the place where he always goes and takes shelter' (Kuçuradi, İ, 1997).
- *The word **Ethos**, as the singular of (Ethe), which means "the place where a living thing shelters, takes shelter," in its first sense, also means character, temperament.*



Principles of Health Care Ethics



Relation of Ethics & Moral-1

- **Ethics** is one of the first 4 basic areas of philosophy:
- *Philosophy of Existency (Ontology), Philosophy of Knowledge (Epistemology), Logic and Ethics.*
- When we look at both the origin of the word **Ethics** and the studies and questions of the philosophers who laid the foundations of philosophy in this field, it is seen that **Ethics is a branch of philosophy.**
- *In this case, **Ethics** is a branch of knowledge. **Morality**, on the other hand, is a social phenomenon that surrounds us from all sides, existing in the outside world;*
- It is a phenomenon composed of various norms, "*commandments*", "*prohibitions*" and "always emerges as the morality of a group, a community".

Relation of Ethics & Moral-2

- **Morality** emerges as "*various value judgment systems*" that change depending on the place and time and have the power of sanction in the society in which it is valid.
- In this case, **Moral** is always the *morality* of, or originates from, a particular community.
- **However, Ethical rules – principles are universal.**



Ethics : The basic concepts and fundamental principles of decent human conduct. It includes study of **universal values** such as the essential **equality of all men and women**, human or natural rights, obedience to the law of land, concern for **health and safety** and, increasingly, also for the natural environment.

The word, «Ethics»

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REVISE THE WORD



A set/system of principles for a culture of an individual.

SENTENCE:

By his actions, he does not seem a very ethical person.

ANTONYMS

dishonesty, evil, corruption

SYNONYMS

honesty, belief, value-system

Fields of Ethics

❑ **Bioethics**

- The study of ethical issues brought about by advances in biology and medicine

❑ **Clinical ethics**

- Analysis of ethical issues and dilemmas in clinical practice

❑ **Research ethics**

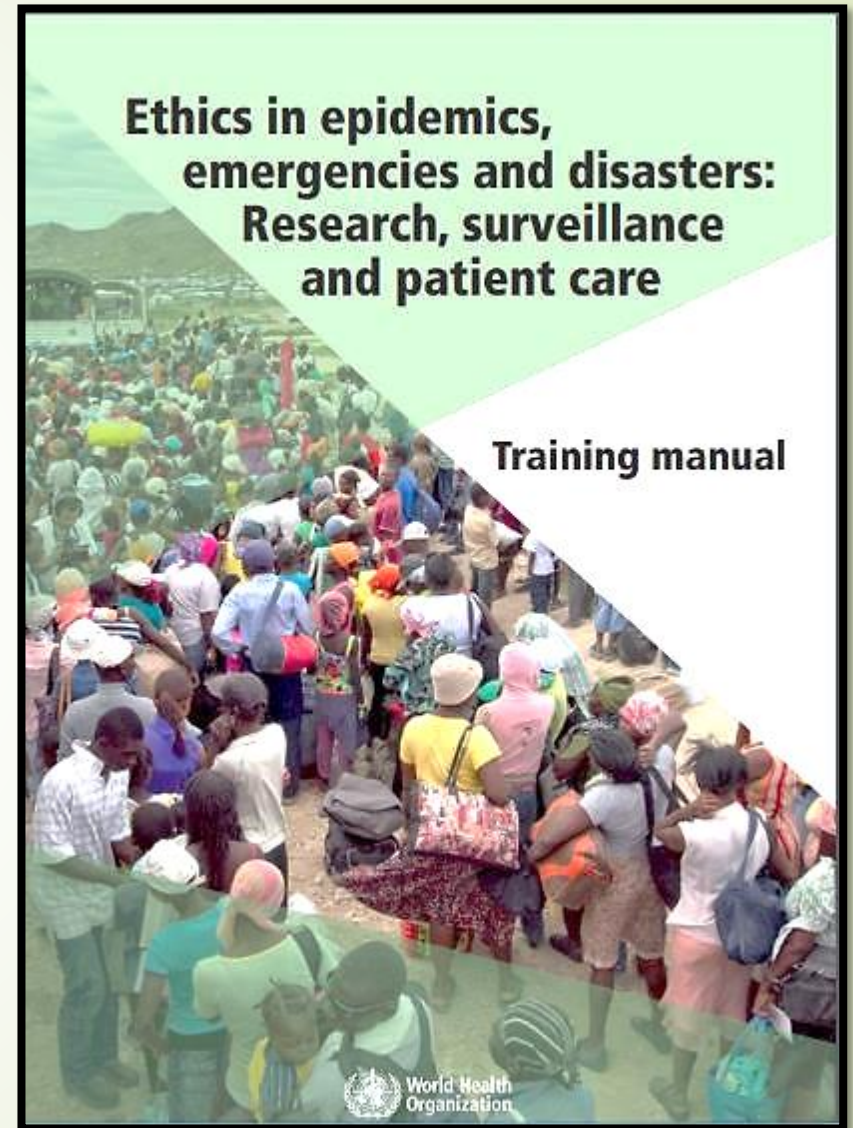
- Protection of research subjects
(in compliance with the Common Rule)

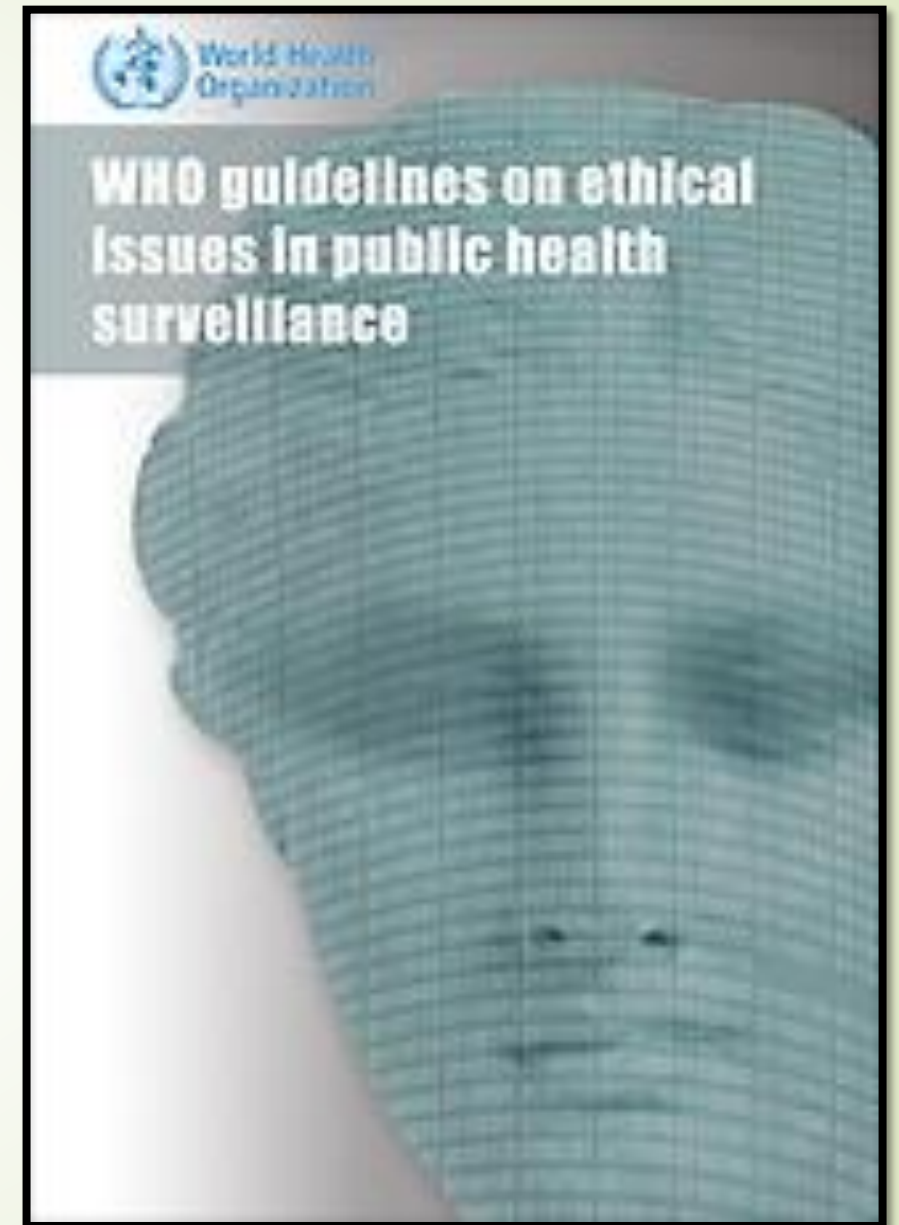
❑ **Public health ethics**

- Practical decision making that supports public health's mandate

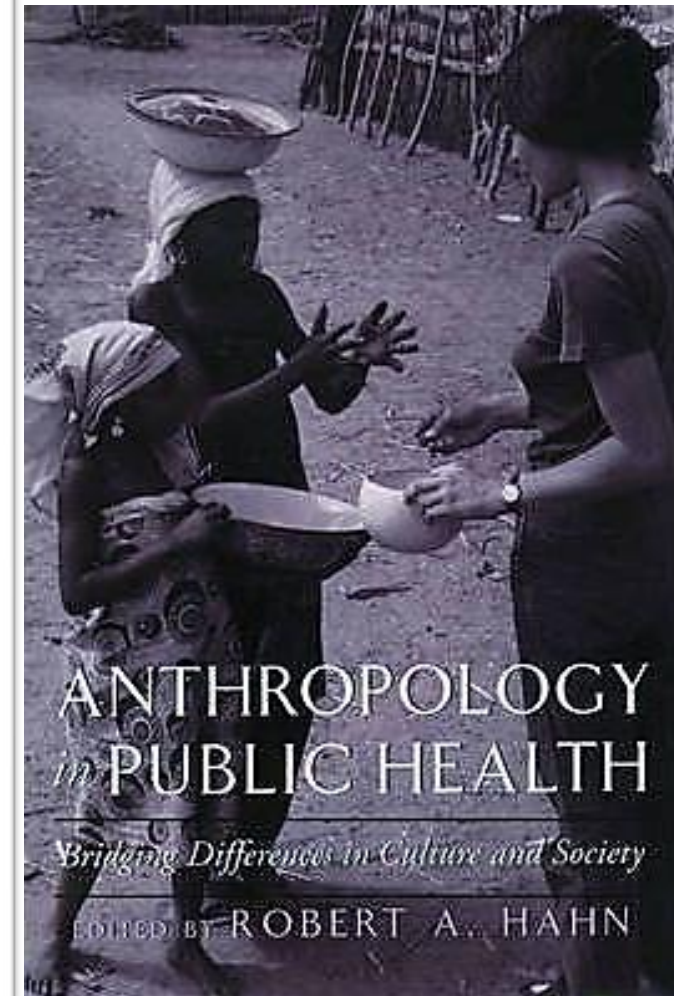
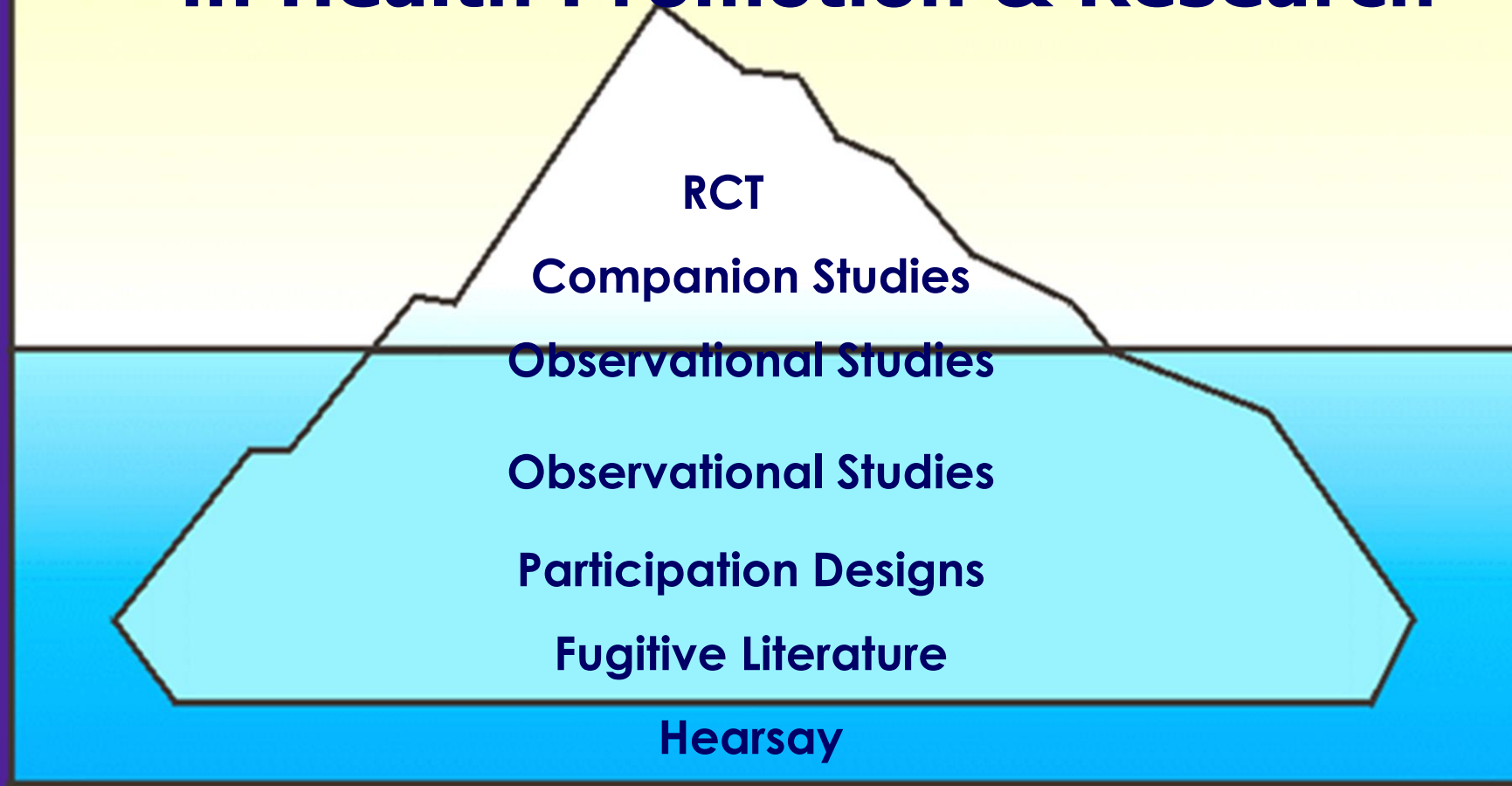


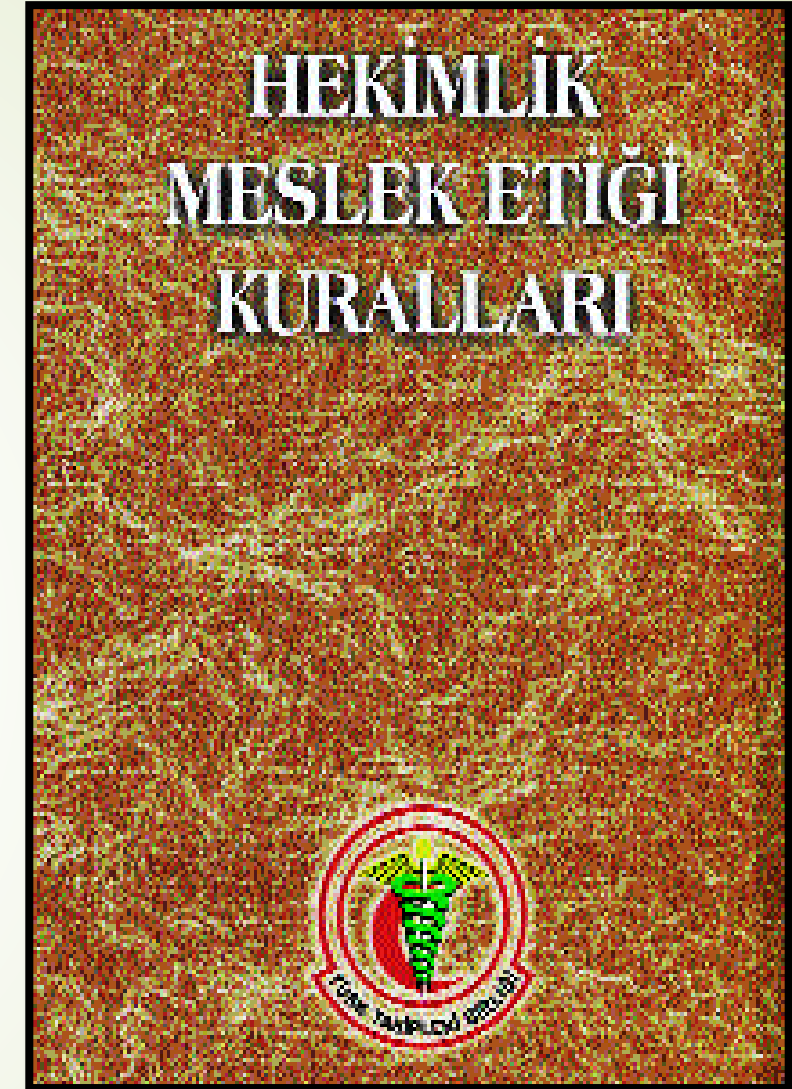
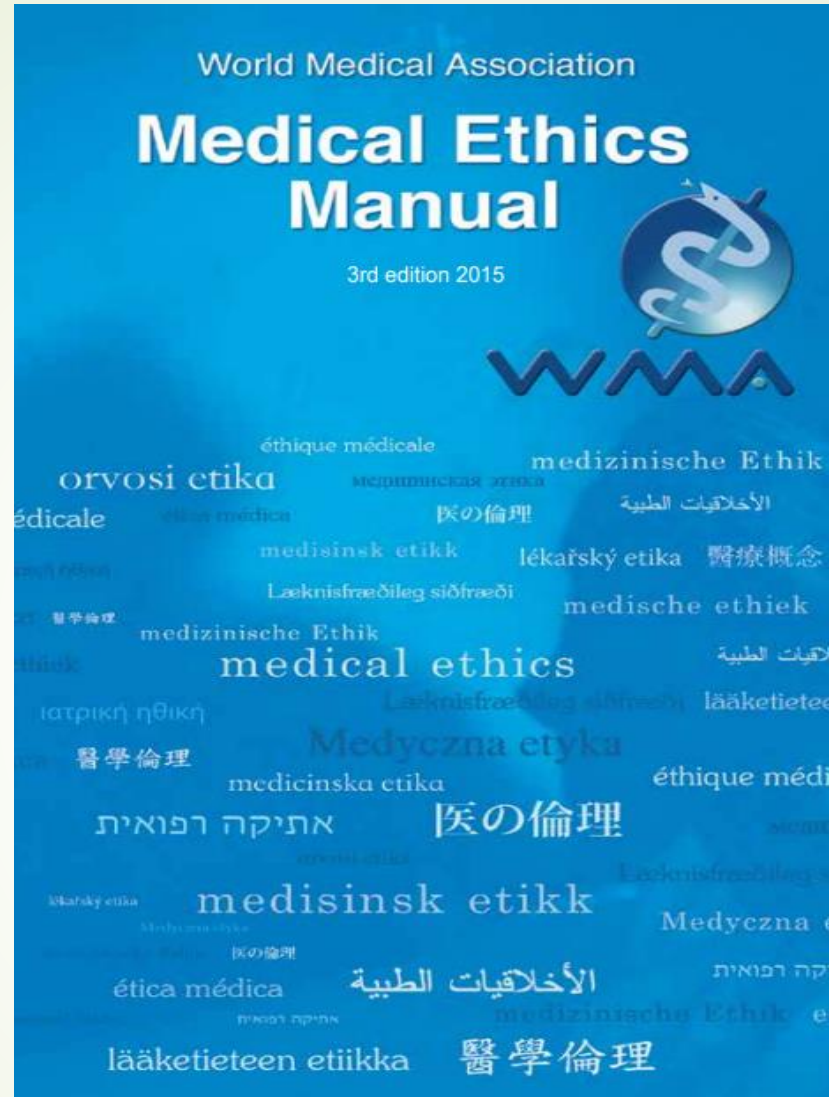
Ethical Challenges





Evidence Iceberg in Health Promotion & Research





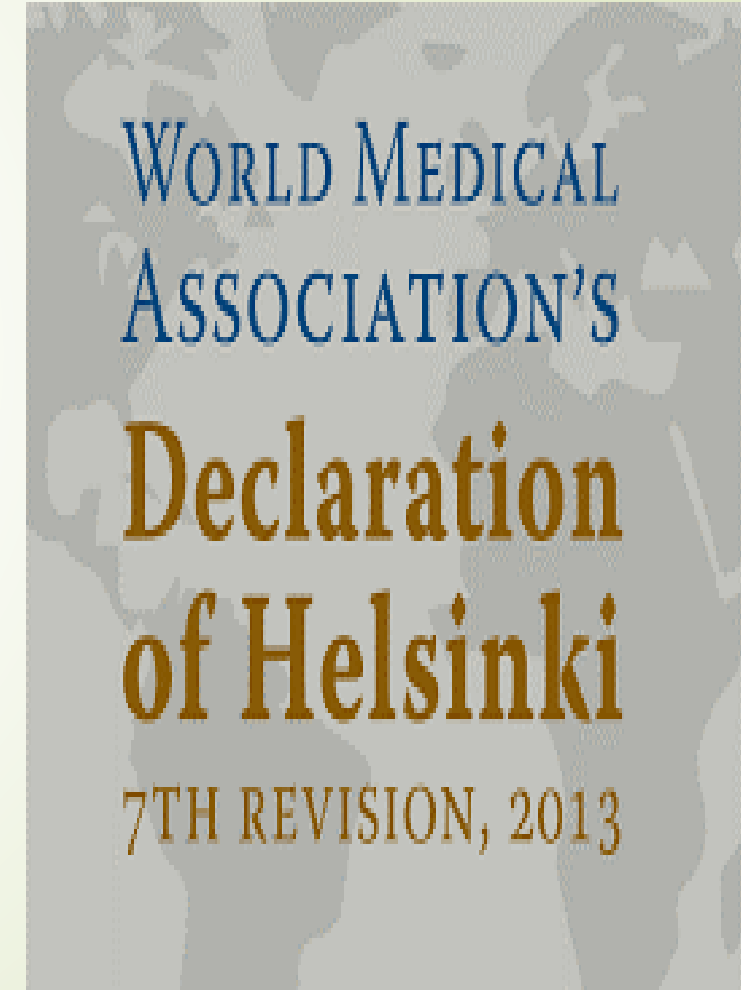
WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

➤ Preamble

- 1. The World Medical Association (WMA) has developed the ***Declaration of Helsinki*** as a statement of ***ethical principles*** for ***medical research*** involving ***human subjects***, including research on identifiable human material and data.
- The **Declaration** is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>



WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

➤ Preamble

- 2. Consistent with the mandate of the **WMA**, the **Declaration** is addressed primarily to physicians.
- The **WMA** encourages others who are involved in medical research involving **human subjects** to adopt these principles.

<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>



WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

➤ General Principles

- 3. The Declaration of Geneva of the WMA binds the physician with the words,
- “The health of my patient will be my first consideration,” and the ***International Code of Medical Ethics*** declares that,
- “A physician shall act in the **patient's best interest** when providing medical care.”

WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

➤ General Principles

- 4. *It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in **medical research**.*
- *The physician's knowledge and conscience are dedicated to the fulfilment of this duty.*
- 5. Medical progress is based on research that ultimately must include studies involving human subjects.

WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

➤ General Principles

- 6. The primary purpose of ***medical research*** involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments).
- Even the best proven interventions must be evaluated continually through research for their ***safety, efficiency, effectiveness, accessibility and quality.***

WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

➤ General Principles

- 7. *Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.*
- 8. While the **primary purpose of medical research** is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

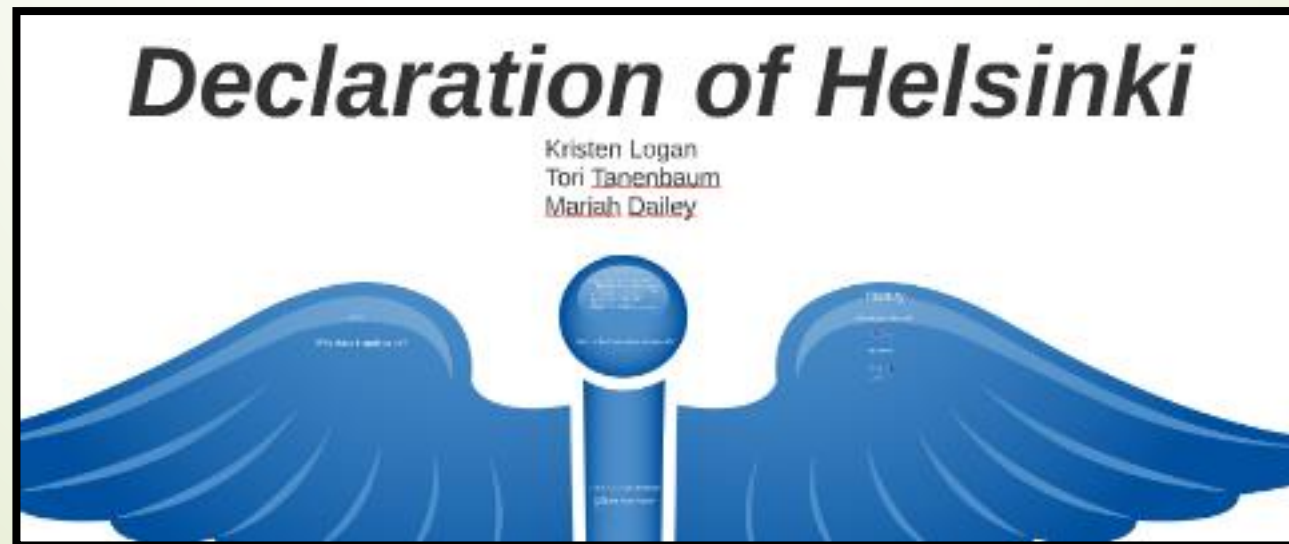
➡ **Unproven Interventions in Clinical Practice**

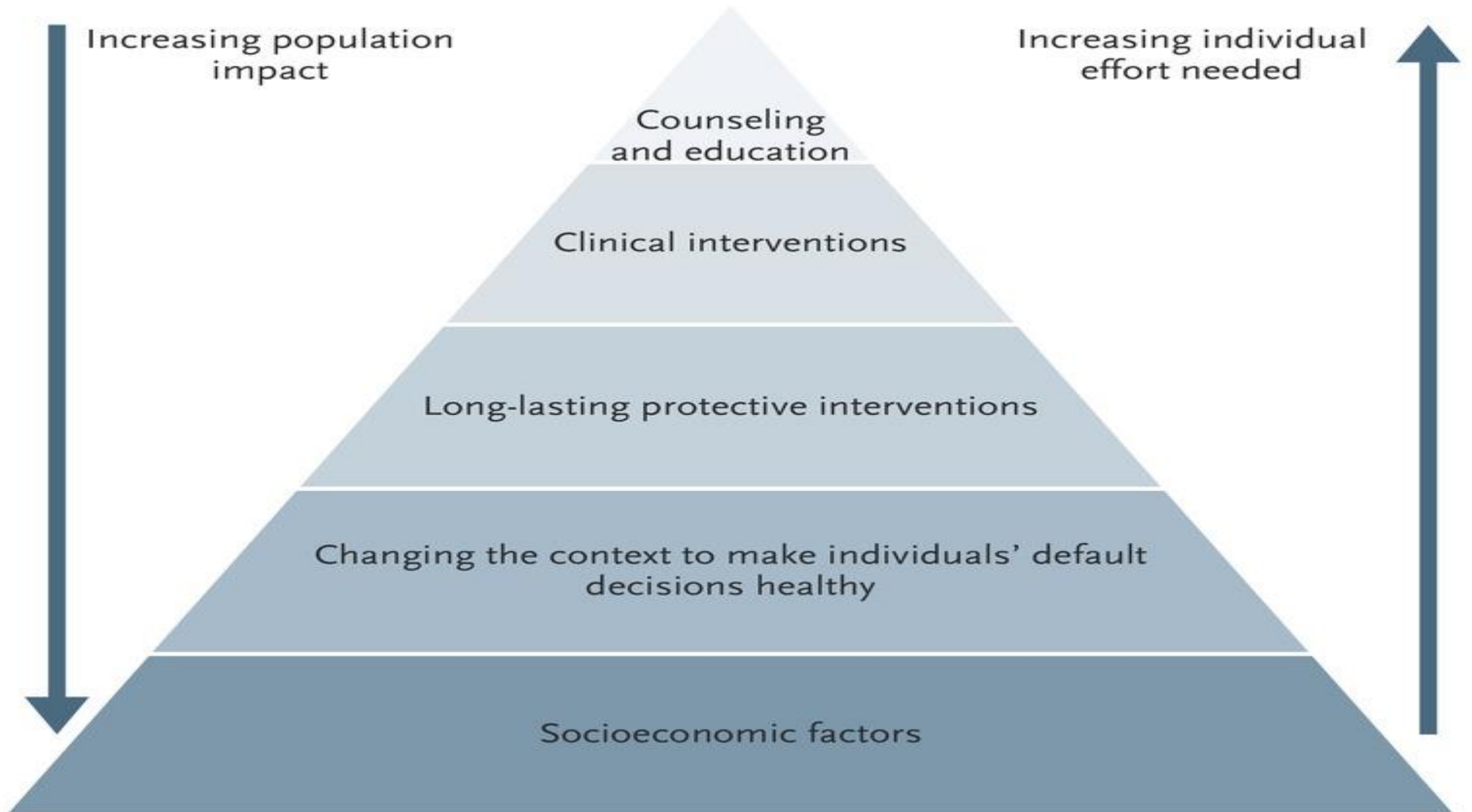
- ➡ 37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective,
- ➡ **The physician**, after seeking expert advice, *with informed consent* from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.

WMA DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

- **Unproven Interventions in Clinical Practice**
- *This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy.*
- In all cases, new information must be recorded and, where appropriate, made publicly available. **9th July 2018**





Experimentation on Human Beings Article 90

(1) Any person who carries out a scientific experiment on a human being shall be sentenced to a penalty of imprisonment for a term of one to three years.

(2) The following conditions must be satisfied to avoid *criminal culpability* in respect of consensual experimentation on a human being:

- a) authorisation from the relevant council or body shall be received;*
- b) the experiment shall first be conducted in an experimental environment (other than the human body) or on a sufficient number of animals,*

Experimentation on Human Beings Article 90

- c) the scientific data obtained through an experiment conducted in an experimental environment (other than the human body), or on animals, should necessitate the experiment then being performed on human beings in order to attain its objectives,
- d) the experiment should not foreseeably damage, or have a permanent effect upon, human health;*
- e) no method should be employed that might result in the test subject suffering to a degree unacceptable to human dignity;
- f) The objective of the experiment should outweigh any danger to the person's health or burden placed upon him; and*
- g) **The consent** of the test subject should be in writing and based on sufficient information about the content and ***consequences of the experiment***, and should not be dependent upon securing any gain.

Experimentation on Human Beings Article 90

(3) *(Amended on 31 March 2005 – By Article 7 of the Law no. 5328)*

In addition to the conditions specified in paragraph two, the following conditions must be satisfied to avoid **criminal liability** for the **experimentation on children**:

- a) the scientific data obtained through an experiment that has been conducted in an experimental environment should necessitate the experiment then being performed on a **child**, in order to attain its objectives;*
- b) **written consent** of the mother and father, or legal guardian, and the consent of the child, where he has the capacity to give consent; and*
- c) the presence of a child health and illness expert (**physician**) from an authorised body (which has the capacity to give permission for the experiment).*

Experimentation on Human Beings Article 90

(4) Any person who conducts a test upon a patient, for the purposes of **medical treatment** (*without receiving the patient's consent*), shall be sentenced to a penalty of imprisonment for a term of up to one year.

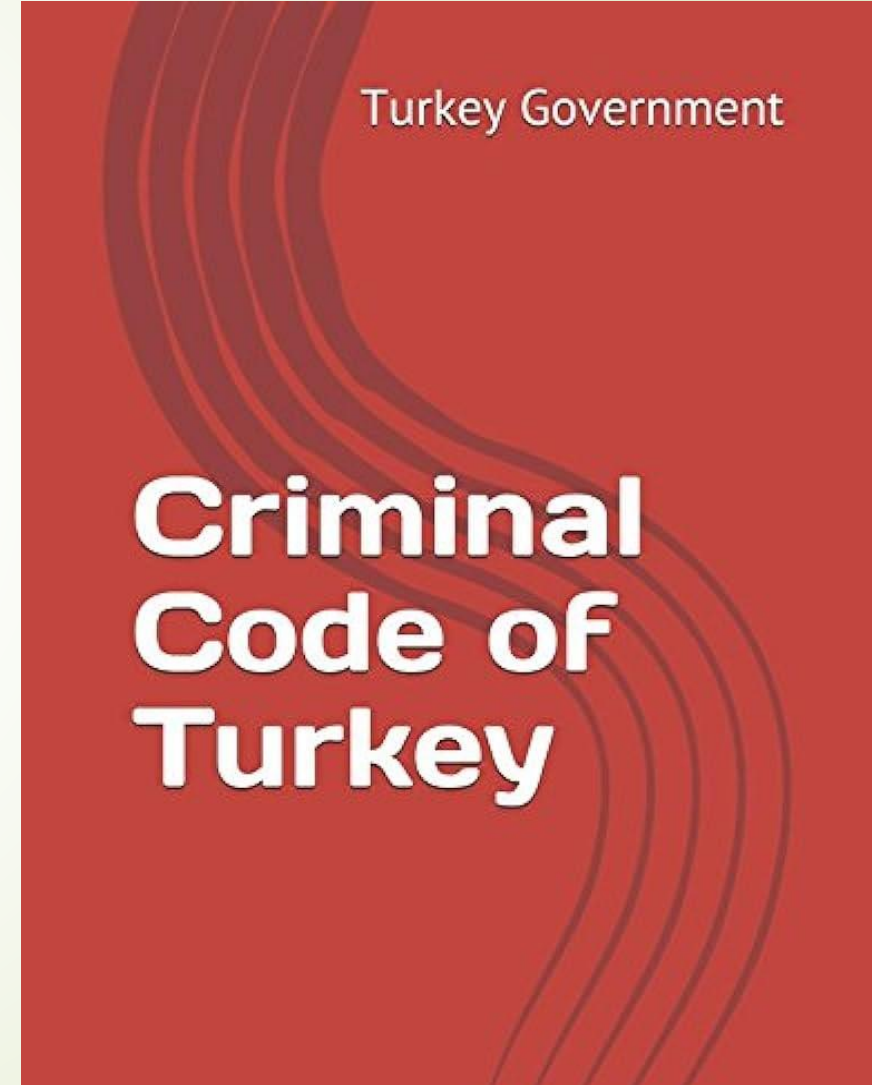
*However, where it is understood that existing methods of known treatment shall not yield any positive results, conducting an experiment, while using known scientific methods, upon a person who has consented to such, with the aim of treating such person, shall not incur **criminal responsibility**.*

The consent should be in writing and be based on sufficient information about the content and consequences of the experiment, and the medical treatment should be conducted by an expert physician in a hospital.

Experimentation on Human Beings Article 90

(5) The provisions pertaining to intentional injury or intentional killing shall be applicable if the victim is injured or dies due to the offence described in paragraph one.

(6) Any offence contained within this article that is carried out within the activities of a legal entity shall result in security measure being imposed upon that legal entity.



CLINICAL STUDIES of MEDICINAL PRODUCTS for HUMAN USE ABOUT REGULATION

ARTICLE 6- (1) **Clinical research;**

It is designed, conducted, recorded and reported in accordance with the most current version of the

World Medical Association

Declaration of Helsinki on Ethical Principles of Medical Research

Conducting Human Subjects

and relevant international standards.



Clinical Trials

The Paul Ehrlich-Institut is the German authority responsible for the evaluation and approval of clinical trials in the field of vaccines and biomedicines. A clinical trial is used to assess the efficacy and safety of medicinal products.

Phase I Trial
A clinical trial in which a medicine is administered for the first time to a few (mostly healthy) people to test the tolerability of the medicine.

Phase II Trial
A clinical trial, often with 100 to 300 participants, to determine the appropriate dose and obtain initial information on the efficacy of the medicinal product against the disease.

Phase III Trial
A clinical trial, usually conducted on a large group of subjects, to gather information about the efficacy and safety of a medicinal product.

Phase IV Trial
A clinical trial to be conducted after authorisation of a medicinal product if necessary.

CLINICAL STUDIES of MEDICINAL PRODUCTS for HUMAN USE ABOUT REGULATION

ARTICLE 6- (1) **Clinical research**;

(2) The following are required in order to conduct **research** on **volunteers**:

- a) In order for the research to be conducted, the research product must first be researched in a non-human experimental environment or on a sufficient number of experimental animals.*
- b) Scientific data obtained as a result of experiments carried out in non-human experimental environments or on animals must make it necessary to carry out these experiments on humans as well in order to achieve the desired goal.

CLINICAL STUDIES of MEDICINAL PRODUCTS for HUMAN USE ABOUT REGULATION

ARTICLE 6- (1) **Clinical research**;

(2) The following are required in order to conduct **research**
on **volunteers**:

c) The *scientific benefits and public interest* expected from the research cannot be prioritized over the health of the volunteers who will participate in the research or the possible risks that may arise in terms of their health and other personal rights.

ç) No research can be conducted to disrupt the genetic structure of the volunteer's germ cells.

CLINICAL STUDIES of MEDICINAL PRODUCTS for HUMAN USE ABOUT REGULATION

ARTICLE 6- (1) **Clinical research**;

(2) The following are required in order to conduct **research** on volunteers:

*d) **Decisions** regarding the medical follow-up and treatment of the volunteer participating in the research belong to the physician or dentist who has the professional qualifications required.*

*e) During the research, it is forbidden to use methods that will cause pain to the volunteer to the extent that it is incompatible with **human dignity**.*

CLINICAL STUDIES of MEDICINAL PRODUCTS for HUMAN USE ABOUT REGULATION

ARTICLE 6- (1) **Clinical research**;

(2) The following are required in order to conduct **research** on volunteers:

*f) **Research**; It is designed to minimize pain, discomfort, fear, and any risks related to the patient's disease and developmental stage. Both the **risk limit** and the degree of discomfort need to be specifically defined and constantly controlled.*

*g) The **purpose** to be achieved by the **research** must outweigh the burden it imposes on the person and the possible danger to the person's health.*

CLINICAL STUDIES of MEDICINAL PRODUCTS for HUMAN USE ABOUT REGULATION

ARTICLE 6- (1) **Clinical research**;

(2) The following are required in order to conduct **research** on volunteers:

*h) If the ethics committee is convinced that the benefits to be obtained are greater than the possible risks arising from the **research**, the research can be initiated after obtaining the approval of the **ethics committee** and the permission of the Institution.*

*i) A duly **informed consent** form must be obtained from volunteers who will participate in the **research**, taking into account their personal rights.*

3) The research is carried out only if the conditions specified in the second paragraph are maintained.

In conclusion...

Ethics Defined: Ethics refers to moral principles that govern a person's behavior or the conduct of an activity.

In the context of medical research, ethical considerations are crucial to ensure the well-being of participants and the integrity of *scientific inquiry*.

***Distinguishing Ethics and Morality:** It's essential to differentiate between ethics and morality. While morality encompasses social order rules that regulate behavior in society, **ethics** encompasses the fundamental principles underlying one's actions.*

Ethical individuals adhere to guiding values, principles, and standards that dictate how things should be done.

In conclusion...

Public Health Ethics:

Understanding public health ethics is vital.

It involves considering the ***ethical implications*** of decisions related to public health services, resource allocation, and community well-being.

Legal Rules on Medical Research: Medical research operates within ***legal frameworks***. ***Students should learn the basic legal rules*** governing research, including ***informed consent***, ***privacy***, and ***data protection***.

Awareness of Legal-Ethical Conflicts: Students must recognize situations where legal and ethical considerations may ***conflict***. Developing strategies to address such conflicts is essential for responsible ***research*** conduct.

In conclusion...

Origin of the Word “**Ethics**”: The term “**ethics**” originates from the ancient Greek word “ethos.” It refers to issues related to the “ethe,” which is the plural of ethos.

Ethos, in its oldest sense, means “*the space of a living being*” or “the place where one takes shelter.” It also signifies character and temperament.

Ethics as a Branch of Philosophy: Ethics is one of the four basic areas of philosophy, alongside **Ontology** (*philosophy of existence*), **Epistemology** (*philosophy of knowledge*), and **logic**. It is a branch of knowledge that explores moral principles and human conduct.

Morality vs. Ethics: While morality is a social phenomenon that surrounds us, **Ethics** is a systematic study of universal values. Ethics encompasses principles like **equality**, human rights, obedience to laws, and concern for health and safety.

In conclusion...

As Learning Objectives : By the end of the lecture, students should:

1. Distinguish between **Ethics** and **Morality**.
2. Understand the *importance of Ethics*.
3. Grasp *Public Health Ethics*.
4. Acquire **key principles** for delivering public health services.
5. Familiarize themselves with legal rules in medical research.

Critical Thinking: Encourage critical thinking about *ethical dilemmas* in *medical research*. Students should learn to navigate complex situations, balancing legal requirements, ethical principles, and the well-being of research participants. Remember that ethical considerations are fundamental to maintaining *trust*, *integrity*, and responsible research practices in the medical field.

ÇOĞU İNSAN
ZEKAYA İNANIR,
BEN İNANMIYORUM.
BİZİ BİRBİRİMİZDEN
AYIRAN EMEKTİR.
BEN ÇALIŞMAYA
İNANIYORUM.

-Aziz Sancar-



*"I beleive in God.,
**Evolution is not a
subject of belief but
a scientific reality.**
You can't roll up the
sun with mud.
*I have no connection
with Creatorists
either."**

Prof. Dr. **Aziz SANCAR**
Nobel laureate



Thanks for all...

*This presentation is recommended to
work with **Health Sociology** slides.*

**Any QUESTIONS?
or COMMENTS??**

f o r

***Thank you
for joining..***



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Motherhood in Childhood

Facing the challenge of
adolescent pregnancy

*No way for child brides &
mothers! It's completely &
absolutely unethical & immoral!
It should legally-strictly banned*



10.03.2024

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