

# 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, 2022 - 23*

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[www.ahmetsaltik.net](http://www.ahmetsaltik.net)

# Learning objectives....

**At the end of this lecture, students are expected to;**

- distinguish between ***Ethics*** and ***Morality***,
- reply the basic questions of ***Ethics***,
- recognize ***Ethics*** as a field of knowledge,
- comprehend the importance of ***Ethics***,
- conceive ***Public Health Ethics***, in particular,
- acquire key principles in delivery of Public Health services,
- learn basic legal rules on medical research
- become aware of legal - ethical conflicts and how to solve..





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



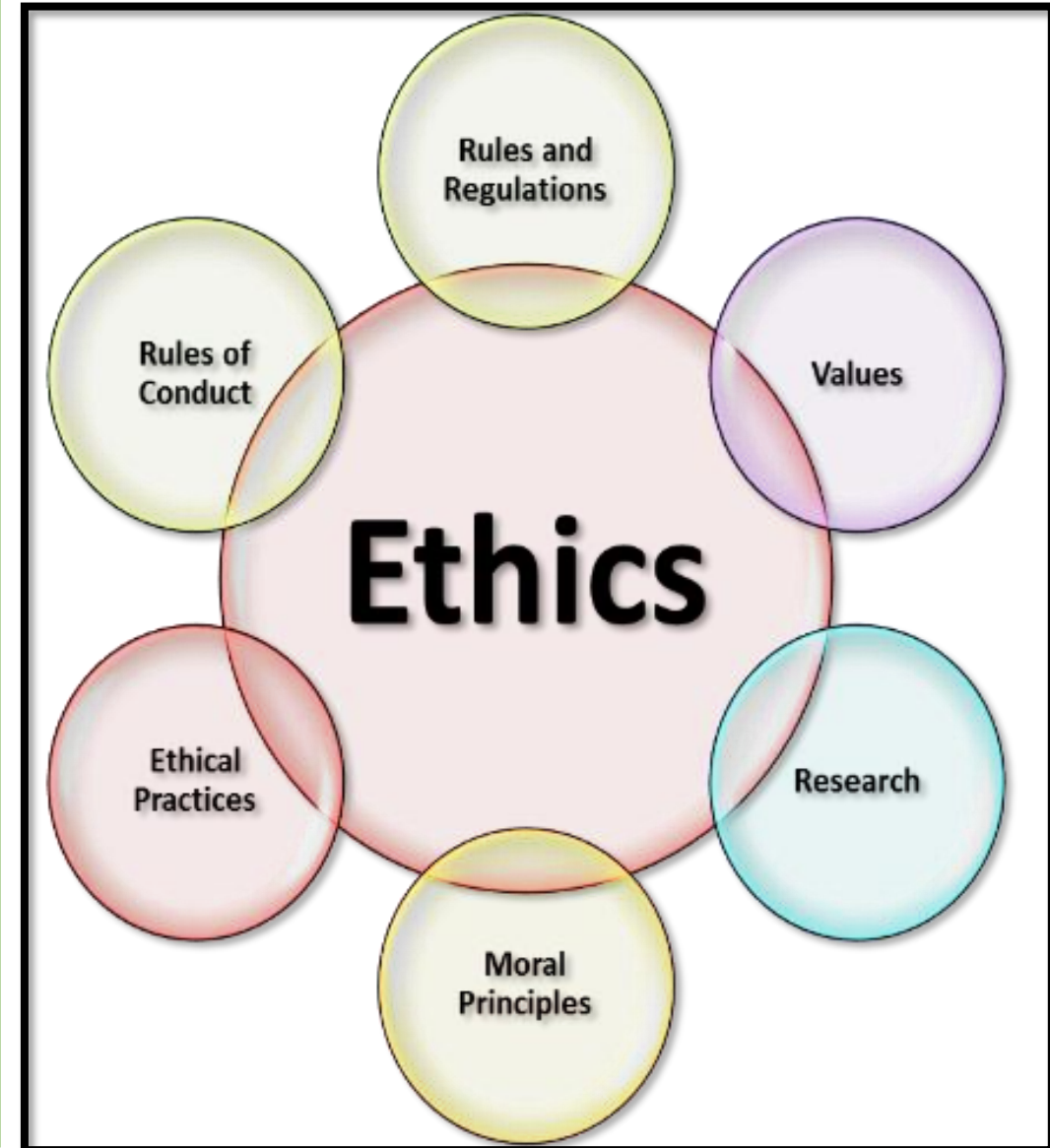


# WHAT IS ETHICS?



# Origin & Meaning of the Word Ethics

- 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*.
- 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.*



- "**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.”*

# ETHICS

Rules of conduct or societal norms with respect to a group or culture.



# MORALS

Habits or behaviors with respect to what an individual believes is right or wrong.



grammarist.com

# Relation of Ethics & Moral

- **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;

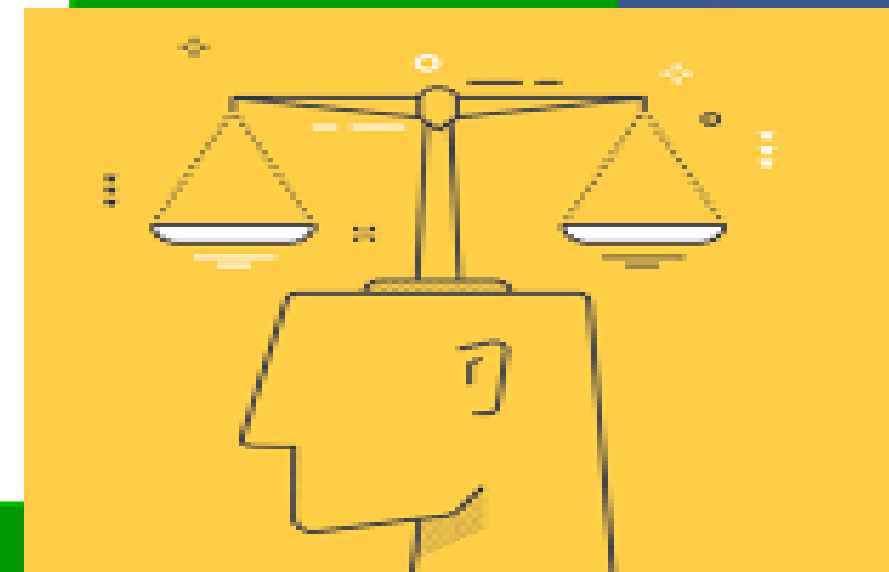


**Ethics** : The basic concepts and fundamental principles of decent human conduct. It includes study of **universal values** such as the essential **equality of all men and women**, human or natural rights, obedience to the law of land, concern for **health and safety** and, increasingly, also for the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



# Relation of Ethics & Moral

- It is a phenomenon composed of various norms, "commandments", "prohibitions" and "always emerges as the morality of a group, a community".
- **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.***



# 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

## ETHICS

Noun



*Ethics refers to a set of principles of right conduct. You need to decide what is right and what is wrong, what is good and what is evil*

# 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





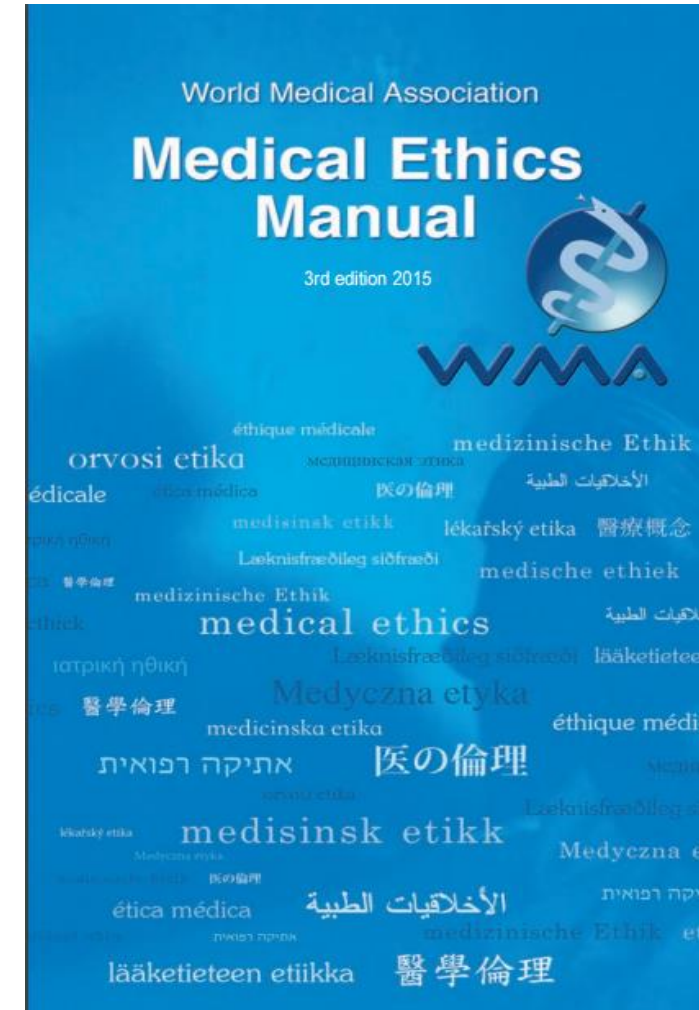
# What is Public Health Ethics?

- A systematic approach to balancing competing interests and providing justification for public health policies and decisions.
  - Often individual rights of autonomy and privacy v. community interests and responsibilities
- “Public health law provides authority to place significant restrictions on individuals; the law describes what public health *can* do, Public Health Ethics helps in determining what public health *should* do.”
  - Alan Melnick, PHLS & Clackamas County (Oregon)  
Public Health Officer



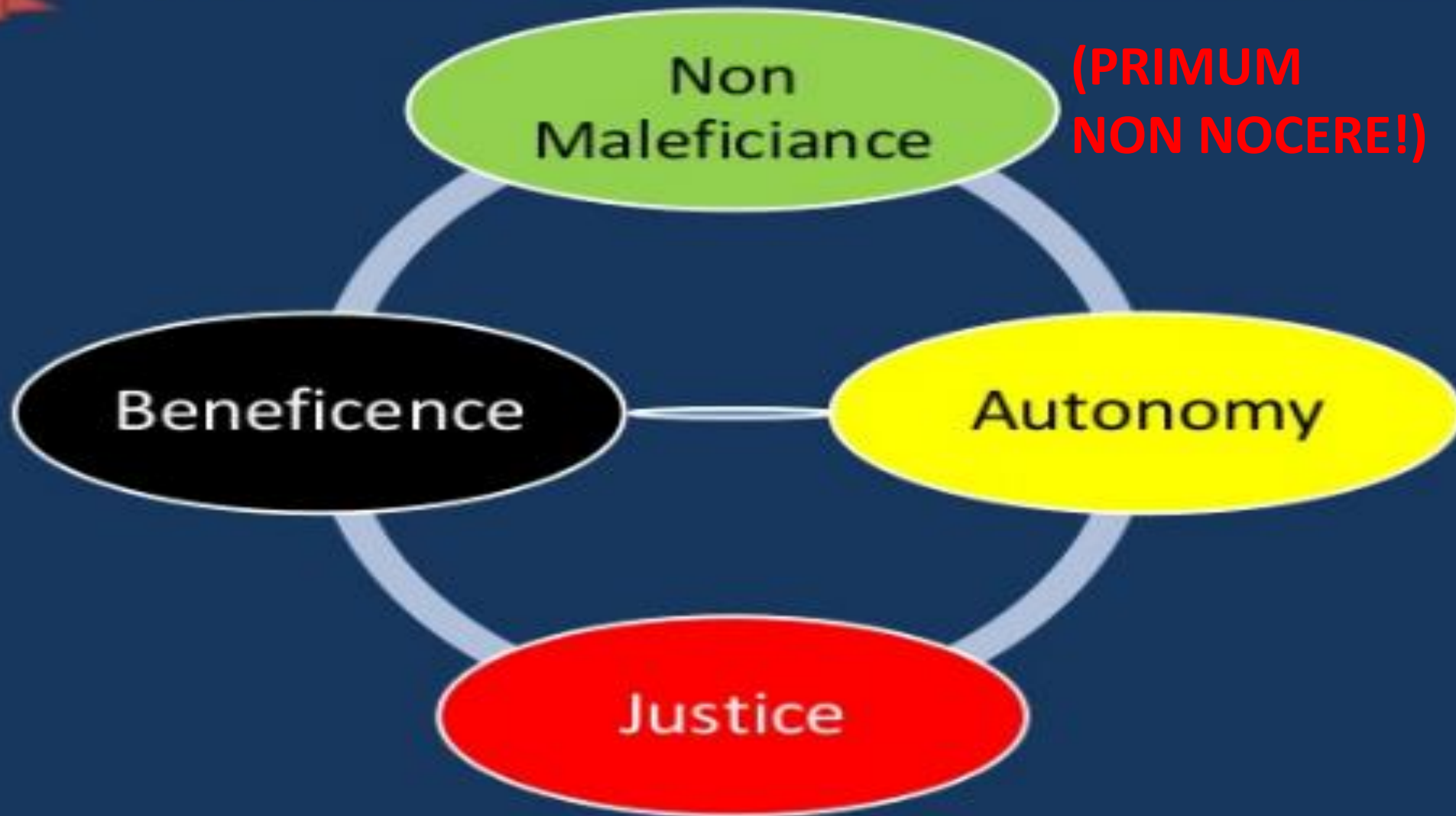
# MEDICAL ETHICS, MEDICAL PROFESSIONALISM, HUMAN RIGHTS & LAW

- ❑ In recent times *medical ethics* has been greatly influenced by developments in *human rights*.
- ❑ In a pluralistic and multicultural world, with many different *moral traditions*, the major international *human rights* agreements can provide a foundation for **medical ethics** that is acceptable across national and cultural boundaries (*WMA- Ethics Manual 3rd edt. 2015*).

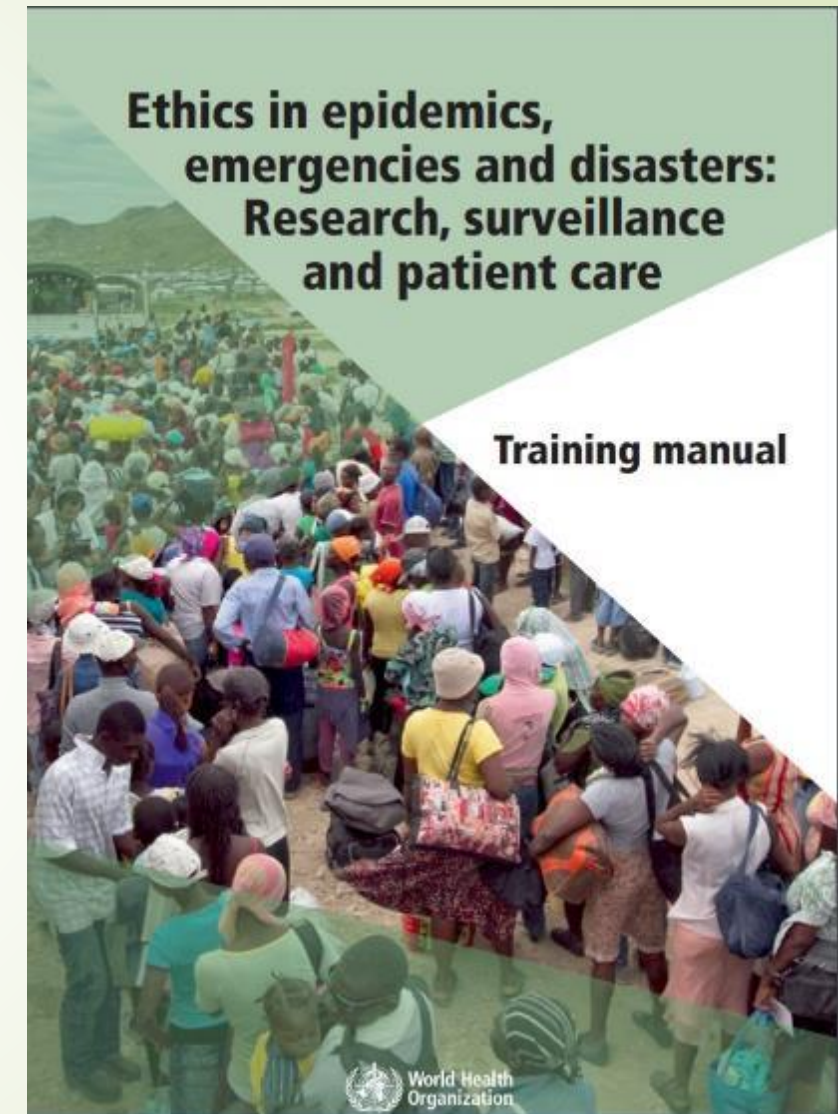




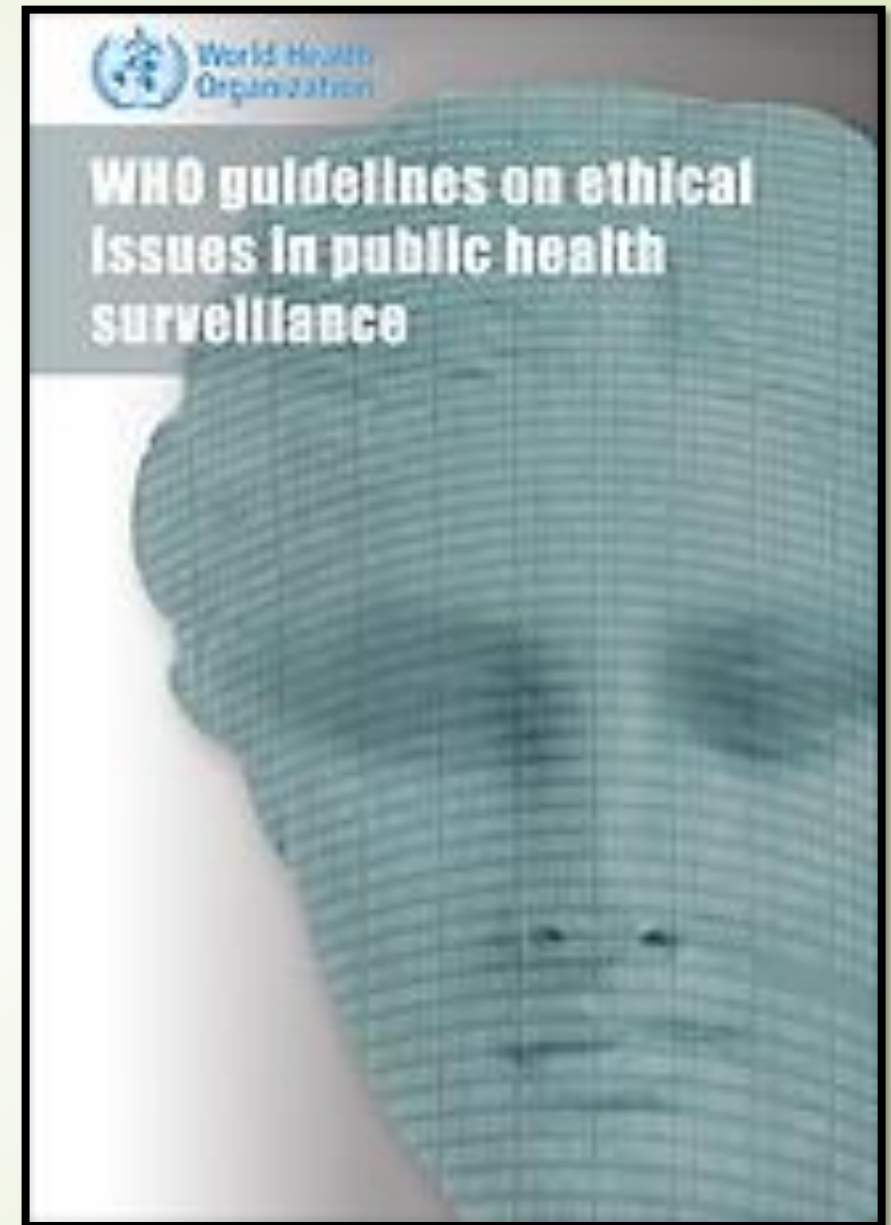
# Principles of Health Care Ethics

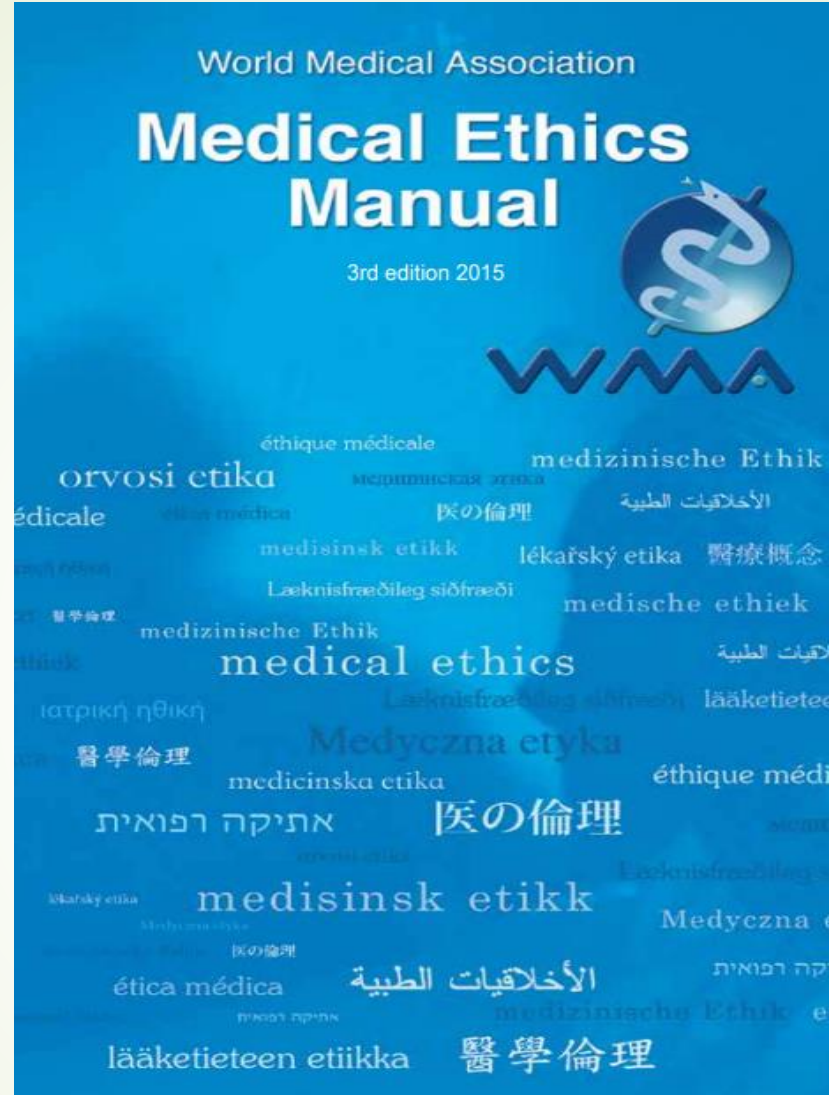


# Ethical Challenges









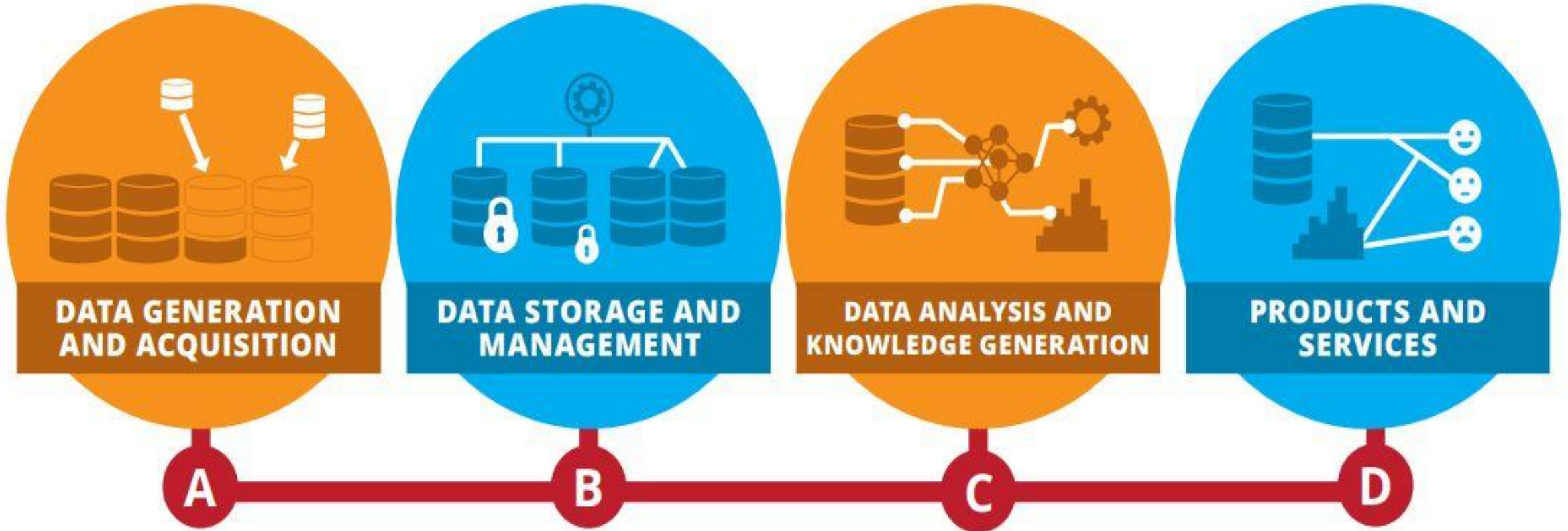
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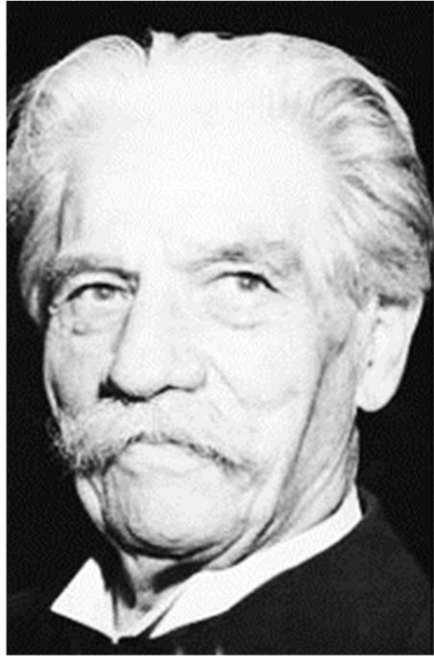




# CODE OF ETHICS

## for Data-Based Value Creation





The first step in the evolution of ethics is a sense of solidarity with other human beings.

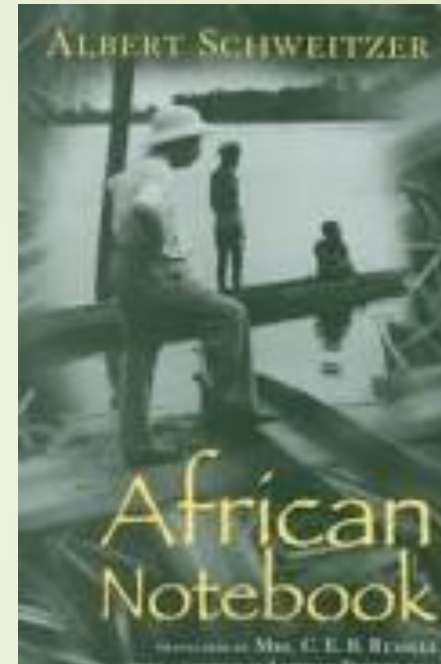
(Albert Schweitzer)

*Wisdom*  
is knowing the right path to take...

*Integrity*  
is taking it

Ethics is nothing else than  
reverence for life.

*Albert Schweitzer*





# WHAT ARE RESEARCH ETHICS?



# WMA DECLARATION OF HELSINKI ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

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## ➤ 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.
- 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.”
- 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.

SENSE  
PRINCIPLES  
WORTHINESS  
MOTIVATION  
FAITH  
RESPONSIBILITY  
INTEGRITY  
HONESTY  
VALUES  
EQUALITY  
SOCIAL  
CONVENTIONALITIES  
TRUTH  
ETIQUETTE  
PERFORMANCE  
FAIRNESS  
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**ETHICS**  
**MORALS**  
**HONOR**  
**RESPECT**  
**PHILOSOPHY**  
**CHARACTER**  
**FAITH**  
**WORTHINESS**  
**RESPONSIBILITY**  
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**DECENCY**  
**CRITERIA**  
**FAIRNESS**

# WMA DECLARATION OF HELSINKI ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

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## ➤ 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, effectiveness, efficiency, accessibility and quality.*
- 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.
- *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)

# Turkish Penal Code / Law # 5237

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## *Use of human for experimental purposes-1*

- **ARTICLE 90-** (1) Any person who uses a person for experimental purposes is sentenced to imprisonment from one year to three years.
- *(2) In order for an experiment carried out upon human under consent not to be subject to a criminal punishment;*
- a) Necessary approval should be received from the competent board or authority,
- *b) The experiment should be initially carried out upon sufficient number of animals without existence of human,*

## *Use of human for experimental purposes-2*

### ➤ **ARTICLE 90-** continued

- c) There should be a need to try human for verification of scientific data obtained as a result of experiments carried out upon animals without existence of human,
- *d) No harmful and steady affects of the experiment should be foreseen on human,*
- e) The method adopted in the experiments should not give pain in such a way to dishonor the person used in the experiment,
- *f) The object tried to be achieved by experiment should be much more important than the risk or burden undertaken by the person,*



## *Use of human for experimental purposes-3*

- **ARTICLE 90**- ...continued..
- g) The **consent of the person** should be obtained in writing by furnishing information about the nature and consequences of the experiment not allowing him to expect any benefit from this experiment.
- ***(3) The children may not be used in experimental purposes.***
- ***(4) Any person who carries out an experiment upon a sick person for treatment purposes without obtaining his consent is punished with imprisonment up to one year. However, where there is no hope to treat a person with ordinary medical means, an experiment based on new scientific methods can be carried out upon a person by obtaining his consent. In such case, no punishment is imposed.***

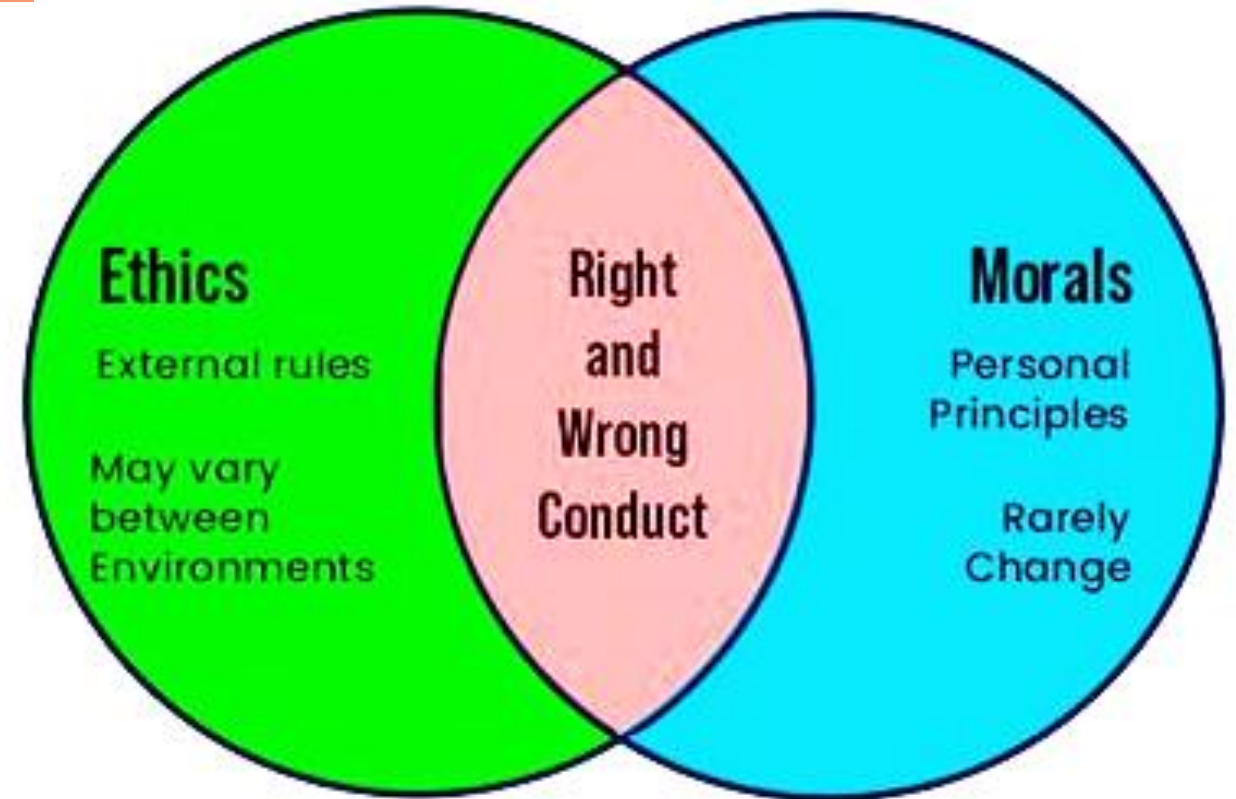
# Turkish Penal Code / Law # 5237

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## *Use of human for experimental purposes-4*

- **ARTICLE 90**- ...continued..
- *This consent should be obtained in writing by furnishing information about the nature and consequences of the experiment and the treatment should be undertaken by a specialist physician in a hospital.*
- (5) The provisions of the Law relating to felonious homicide and felonious injury are applied in case of injury or death of the victim following the commission of the offense defined in first subsection.
- *(6) The security precautions specific to legal entities are applied in case of commission of offenses listed in this section within the frame of the activities of a legal entity.*











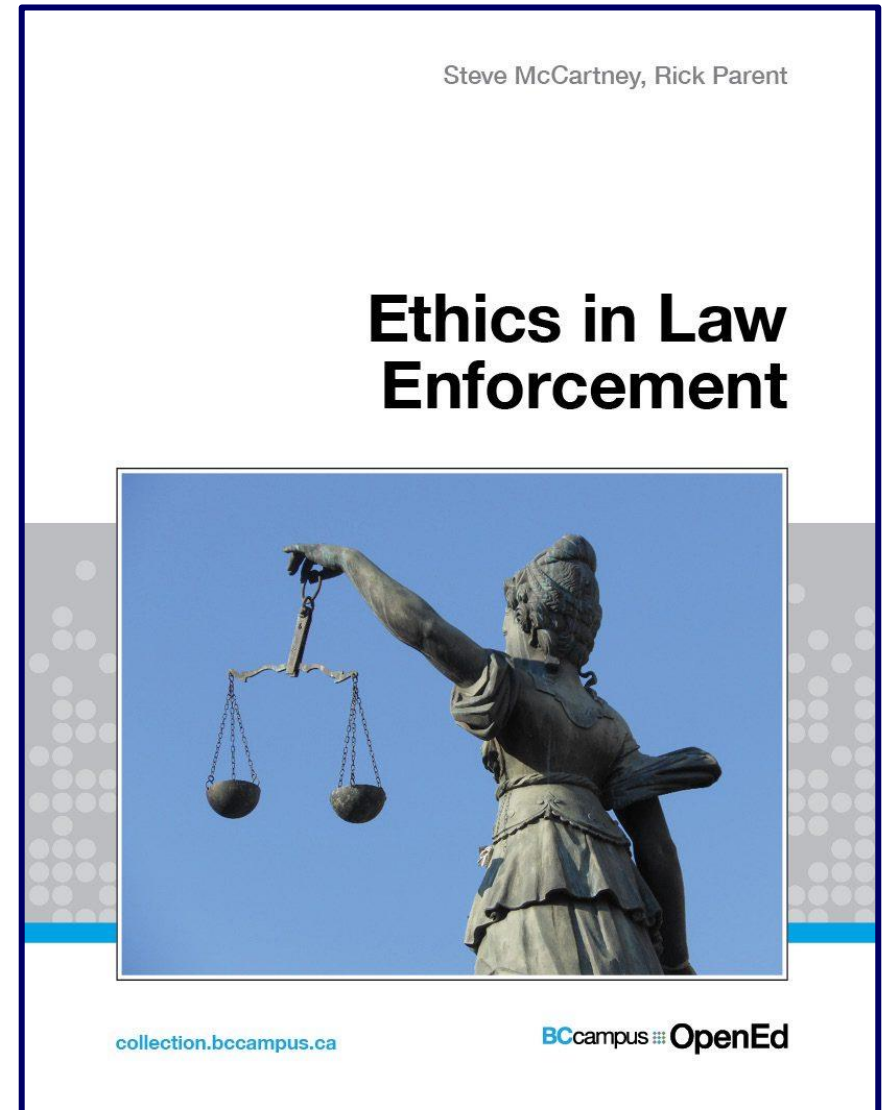
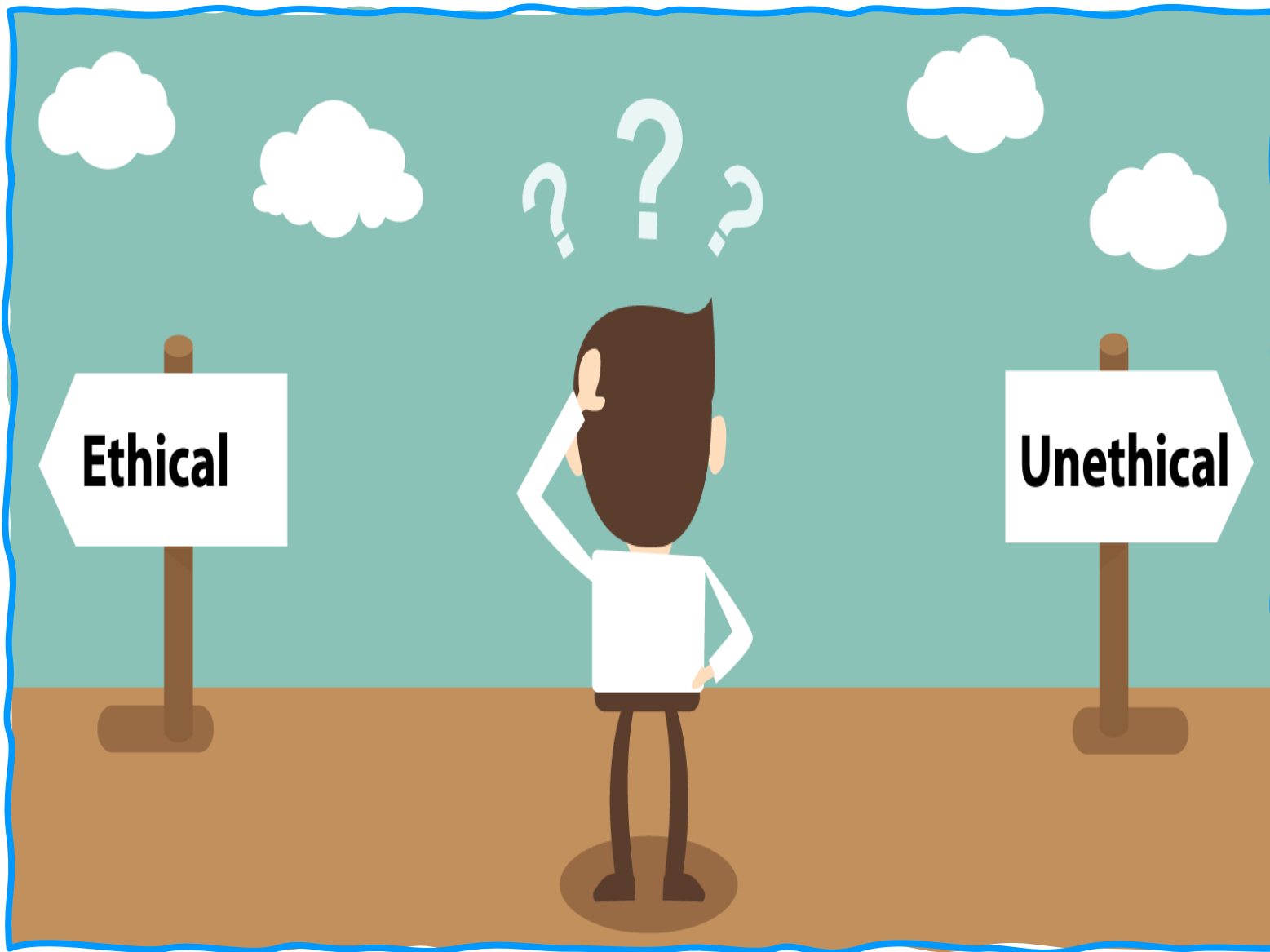
HOW SHOULD I BE?



HOW SHOULD I ACT?



WHAT IS MY  
RESPONSIBILITY?

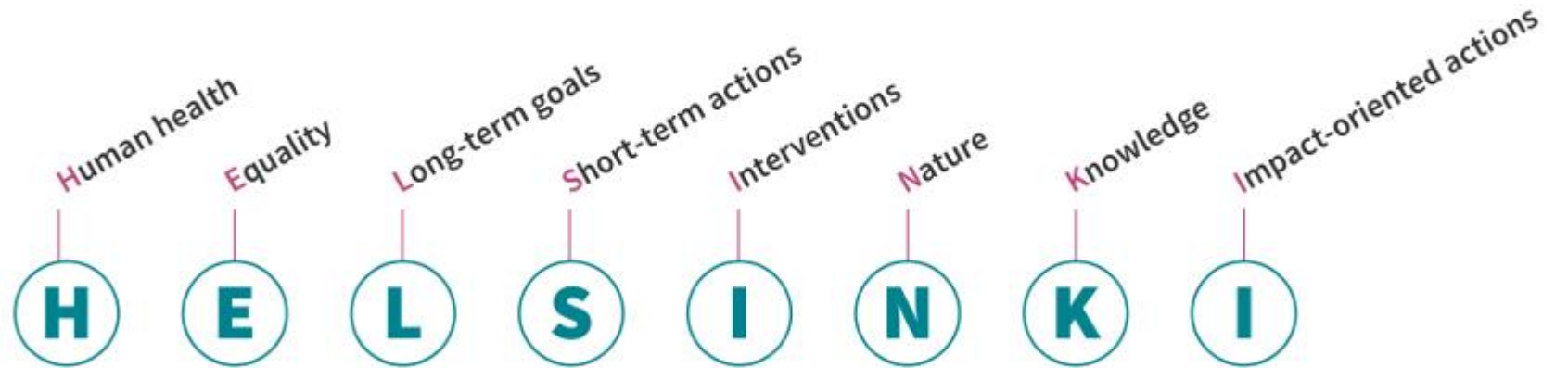




# Declaration of Helsinki

MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

**Helsinki declaration** to protect human  
and planetary health for 2020's

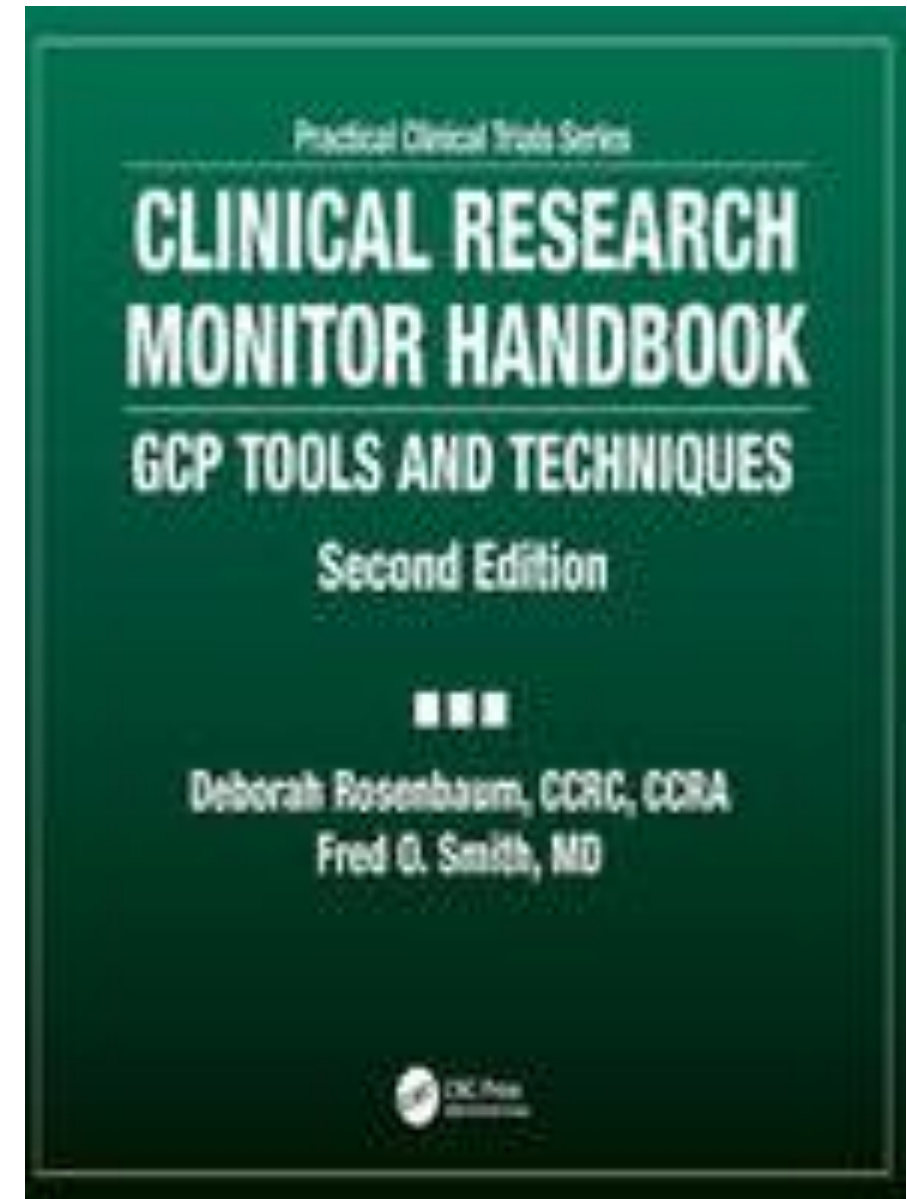


# Basel Declaration on Animal Research

Preamble + 3Ss + 4Fs



Unified Principles







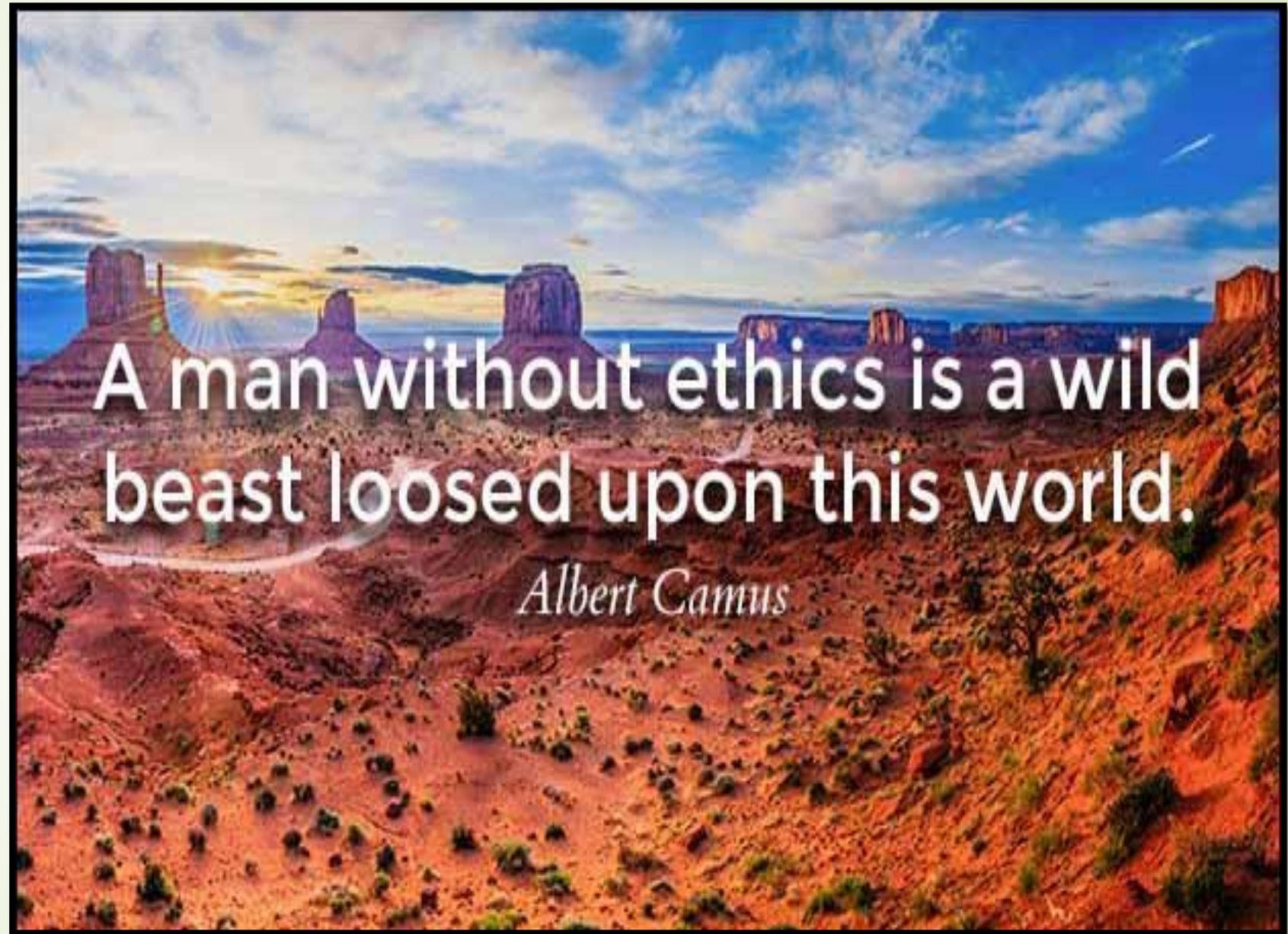
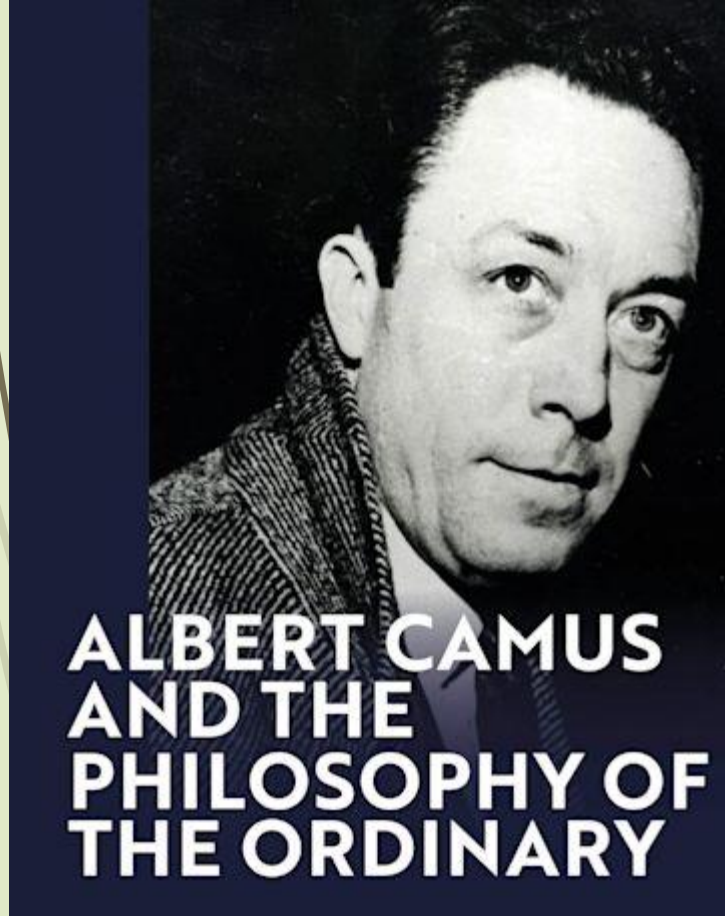
# Code of Ethics

*['kōd ōv 'e-thiks]*

A set of rules and principles designed to encourage ethical conduct among a group of professionals.











***Thank you  
for joining.***

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Slides also available at :  
**[www.ahmetsaltik.net](http://www.ahmetsaltik.net)**

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