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Ethical Principles and Responsibilities in Medical Research



ALWAYS



SEEK



KNOWLEDGE

Objectives

- Historical
- Principles
- Ethic comitee
- Research fraud

Historical

Sources of ethical thought:

- religious tradition
- philosophical thought
- medical practice

Historical

- codes of conduct
 - for medical profession

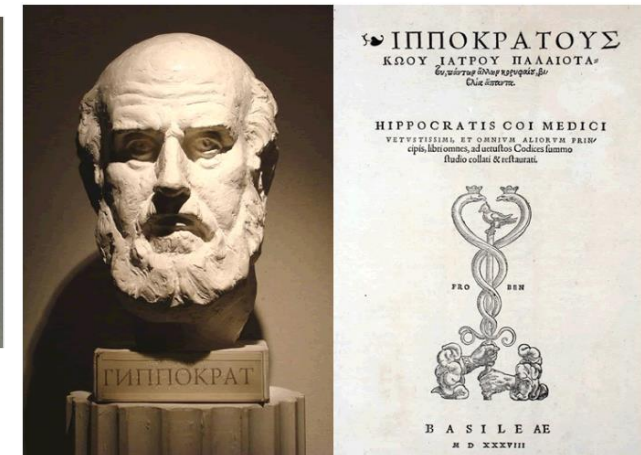
Hammurabi code of medical ethics	1700 B.C.
Charaka code of medical ethics	600 B.C.
Hippocratic code of ethics	400 B.C.
AMA (American Medical Association) code of ethics	1846
GMC code through an act of the british parliament	1858
German ethics of science and medicine	1898
Nuremberg code of ethics	1947
Universal declaration of human rights	1948

P Chandramohan. Ups and downs in the history of medical ethics. Archives of Medicine and Health Sciences. 2013,1(2):191

- or for other professions
 - Legal codes
 - 2400 BC legal code (Syria) – the oldest
 - Sumerian Code of Ur-Nammu (c. 2100–2050 BC),
 - Babylonian Code of Hammurabi (c. 1760 BC)
 - etc.



1700 BC
Code of Hammurabi



400 BC
Code of Hippocrate

1947

THE NUREMBERG CODE

1. VOLUNTARY CONSENT IS ESSENTIAL
2. THE RESULTS MUST BE FOR THE GREATER GOOD OF SOCIETY
3. HUMAN EXPERIMENTS SHOULD BE BASED ON PREVIOUS ANIMAL EXPERIMENTATION
4. EXPERIMENTS SHOULD BE CONDUCTED BY AVOIDING PHYSICAL/MENTAL SUFFERING AND INJURY
5. NO EXPERIMENTS SHOULD BE CONDUCTED IF IT IS BELIEVED TO CAUSE DEATH/DISABILITY
6. THE RISKS SHOULD NEVER EXCEED THE BENEFITS
7. ADEQUATE FACILITIES SHOULD BE USED TO PROTECT SUBJECTS
8. EXPERIMENTS SHOULD BE CONDUCTED ONLY BY QUALIFIED SCIENTISTS
9. SUBJECTS CAN FREELY END THE EXPERIMENT
10. THE SCIENTIST IN CHARGE MUST BE PREPARED TO TERMINATE THE EXPERIMENT WHEN INJURY, DISABILITY, OR DEATH IS LIKELY TO OCCUR.

Ethical principles for research 2026

- Conflict of interest
- Confidentiality
- Respect for others
- Autonomy
- Dignity
- Honesty
- Do no harm
- Principle of advantage
- Principle of justice
- Research involving the use of animals
- Research involving human subjects
- Programs involving biological risks, using radioactive materials, chemical agents, or having an impact on the environment

Conflict of interest

- financial
 - relationships with a firm that has a stake in the subject
 - grants, funding, salaried income received by the authors or by their immediate family members
 - any current negotiations regarding future employment
- non-financial
 - relationships
 - with those who might be helped or hurt by the research
 - with a private sector entity,
 - any affiliations that may be relevant
 - boards and advisory panels members
 - academic interests
 - any personal, religious or political convictions relevant and expressed in public
- In any of these circumstances, the researcher must declare the existence of a conflict of interest

Respect for others

- honestly **respecting** of individuals capable of making clear decisions and able to exercise their free will
 - the autonomy
 - dignity
- **protection** of individuals incapable or whose decision to participate in research is seriously compromised

Do no harm

- the obligation of researchers to
 - prevent experiments that lead to suffering of the subjects
 - eliminate/finish experiments that lead to suffering of the subjects
- the prohibition of any manifestations that affect the integrity of the person
 - torture
 - genocide
 - exploitation of vulnerable groups
- respect the principle
 - of autonomy
 - of normal acceptable risk

Advantage Principle

- legitimacy of the research
 - research provide advantages for
 - participants
 - society
 - enrichment of knowledge

The principle of justice

- the equitable distribution of the advantages and disadvantages of research
- research involves participants
 - from vulnerable categories
 - categories incapable of protecting their own interests
- susceptible to being
 - exploited
 - neglected

"The Nuremberg Code"

An author is a person

- capable of decisions making
- sufficient informed regarding
 - the consequences of the research
 - all possible options for change
- must not be influenced by
 - external factors
 - force
 - deception
 - coercion

Research must be evaluated by a Professional Ethics Committee if:

Research projects that imply the use of

- experimental animals,
 - human subjects,
 - high-risk biological preparations,
 - radioactive materials
 - toxic chemical compounds
- or that may have a negative impact on the environment

Professional Ethics Committee

- established at the education institution, public or private research institute, hospital.
- The ethics committee must comprise at least 5 members:
 - 2 members with extensive knowledge in the fields of research;
 - 1 ethics expert;
 - 1 lawyer;
 - 1 member from civil society

Professional Ethics Committe

- ensuring compliance with the Code of Ethics of the research projects
- protecting participants
- respecting the rights of researchers

Programs/research requiring the use of animals

Animals may be used in research programs:

- Only if institutions have failed to find an alternative
- The smallest possible number of animals are used
- When the health and safety of the research team working with animals is ensured

Research requiring human subjects

- experimental activity - must be explained to the subjects
 - purpose
 - utility
 - desirable benefits
 - methods
 - risks
 - possible alternative procedures

Research requiring human subjects

- subjects must be informed
 - of the factors that may lead them to refuse to take part in the experiment
 - of their right to withdraw at any time without being subjected to any coercive method,
 - that the confidentiality is respected
- **written** consent must be obtain

Programs that involve biological risks, use radioactive materials, chemical agents and/or have an impact on the environment

- Institutions must ensure that research teams have been informed and are aware of the risks of accidents (e.g. activity with chemical agents or radioactive materials, etc.)
- Teams are adequately trained, benefit from protective equipment and security measures are strengthened.
- The storage and provision of all these materials must comply with the legislation in force - European Union standards.

Fraud in research

What is fraud?

- Inventing data or cases
- Falsification: Willful alteration of data
- Failing to report missing data
- Failing to include adverse event data in clinical trials

What is fraud?

- Plagiarism: Copying data or articles
- How much is still allowed?
- Theft of ideas?
- Redundant publishing
- Failure to declare a conflict of interest
- Omission or addition of authors

Committee on Publication Ethics (COPE)

- Founded in 1997 in response to concerns about the integrity of authors publishing in medical journals
- Founded by British medical publishers including BMJ, Gut Lancet

COPE Objectives

- Advice for publishers dealing with cases of fraud
- Publish an annual report on cases of fraud
www.publicationethics.org.uk
- Publish guidelines for fair research
- Encourage honest research
- Educate on research ethics

The first 103 COPE cases

- In 80 cases there was clear evidence of fraud:
 - Undeclared redundant publication (29),
 - Copyright disputes (18)
 - Forgery (15)
 - Failure to obtain informed consent (11)
 - Unethical research (11)
 - Failure to obtain research ethics committee approval (10)

Thank you!