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**INTERNATIONAL CONFERENCE
ON PATIENTS' RIGHTS**

Informed Consent as a core element of patient autonomy

Protection of Human Rights in Biomedicine III Project





- Informed consent is a legal and ethical requirement in healthcare
- It upholds patient autonomy, a fundamental principle in medical ethics.
- Society's commitment to protecting individual liberties



Core principles of the Oviedo Convention



- Human dignity and primacy of the person
- Informed consent
- Non- discrimination
- Equitable access to health care
- Protection of persons lacking capacity
- Right to private life and information
- Protection in biomedical research



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Oviedo Convention: Article 5 – General Rule on Consent

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.



Article 5 – General Rule on Consent

1. An intervention in the health field requires free and informed consent.
2. Informed consent previous to the intervention
3. Given to the person concerned
4. Patient must receive adequate information (purpose, nature, risks, consequences).
5. Consent may be withdrawn at any time.



Explanatory Report

<https://rm.coe.int/1680a8e4d0>
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The patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone



Paternalist model



Shared decision



FREE



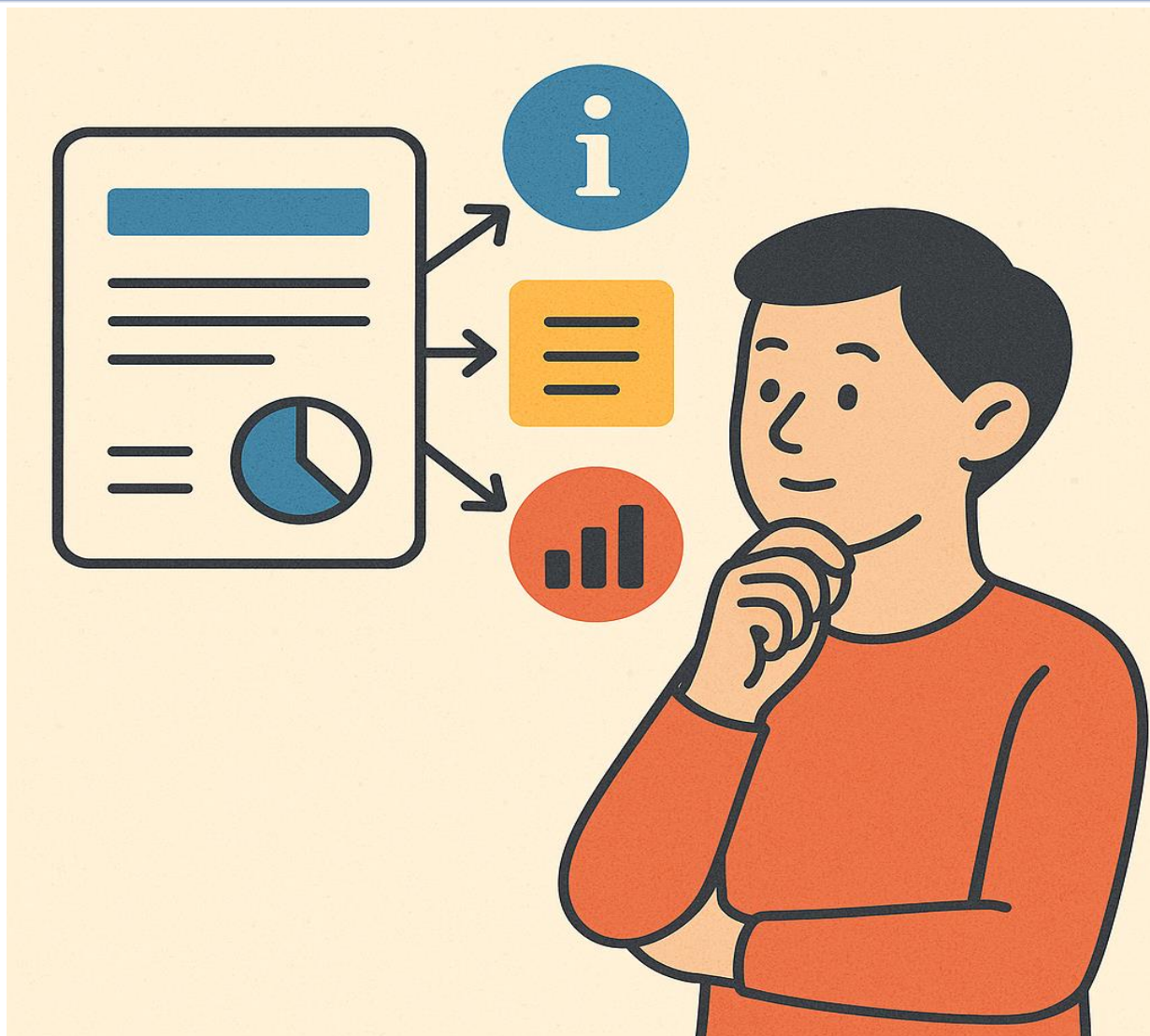


SPECIFIC





INFORMED





INFORMED

- affirmation of a right to information
- before the intervention
- appropriate (to the purpose and nature of the intervention)
- about the relevant facts regarding the intervention:
 - a) purpose, nature and consequences of the intervention
 - b) the risks involved
 - c) sufficiently clear and suitably worded for the person who is to undergo the intervention



A few EXCEPTIONS

- **Emergency situations** (v. art. 8 Oviedo Convention)
- **Previously expressed wishes** (v. art. 9 Oviedo Convention)
- **People not able to consent** (v. art. 6 Oviedo Convention)



Practical Challenges

- Time constraints in clinical practice.
- Health literacy and communication barriers.
- Cultural differences.
- Balancing autonomy with beneficence.



Implications for Healthcare Professionals

- Duty to inform and communicate effectively.
- Need for training in consent processes.
- Ethical responsibility to respect autonomy.



Implications for Institutions

- Policies ensuring compliance with the Convention.
- Documentation standards.
- Support for vulnerable patients.
- Adequate conditions for implementation.



ECHR recent jurisprudence (informed consent related to health)



- **Mayboroda v: Ukraine, n° 14709/07 (2023)**

The Court found a violation of article 8 (European Convention of Human Rights) because the State failed to protect the applicant's right to informed consent before a surgical intervention that resulted in the removal of her kidney.

The Court explicitly links lack of informed consent to an interference with private life.



Actual and New challenges

- Not an “YES” or “NO” action (the choice to take preventive measures, to ask for a second opinion, and to exercise the “right not to know”)
- Protection of persons not able to consent
- Use of digital tools
- Use of digital consent tools
- Biomedical Research
- The use of AI systems and its applications in the patient-doctor relationship (<https://rm.coe.int/cdbio-2023-7-rev3-ai-report-new-banner-e/1680b1bfe4>)



AI and informed consent

- Patients need:
 - ▶ to be more aware and critical of AI systems used in their health care;
 - ▶ to know when they are interacting with an AI system;
 - ▶ to be clearly informed and explained about the use of AI in cases which matter to them;
 - ▶ to be able to accept or refuse AI in their care or treatment, and to this end seek a second opinion without the use of an AI-system, where possible.



conclusion

Continued fight for law and human dignity

*Adopted by the institutions to
human dignity*



Merci !



Paula Martinho da Silva paulamartinhos@outlook.pt