

# Ethical and Legal Perspectives on Informed Consent in the Context of International Human Rights Law

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**Abstract:** *This article examines the concept of informed consent from bioethical and legal perspectives, analyzing its evolution as a distinct legal institution within international medical law. The study explores informed consent's dual role as a decision-making process and administrative tool in medical practice and human subject research, emphasizing its importance in protecting patient rights and autonomy. The analysis traces the philosophical foundations of informed consent from Kantian thought to contemporary interpretations, highlighting its development in international human rights law and European Union legislation. Key legal instruments and ethical declarations are discussed, including the UN Charter, Universal Declaration of Human Rights, Oviedo Convention, and Declaration of Helsinki. The article argues that informed consent has transcended its origins in civil law to become a complex, unilateral legal act specific to the medical field. It examines the tension between contractualist perspectives on the doctor-patient relationship and the unilateral nature of informed consent, emphasizing the latter's role in protecting individual autonomy and self-determination. Challenges in implementing informed consent are addressed, including adapting information to patients' understanding and ensuring truly voluntary decisions. The study also explores medical liability, distinguishing between obligations of means and results in medical practice. Through analysis of European Court of Human Rights jurisprudence, the article demonstrates the evolving interpretation of informed consent in relation to privacy rights and patient autonomy. It concludes by affirming informed consent's transformation into a distinct legal-social practice, reflecting growing recognition of individual autonomy in medical decision-making and the need to balance professional obligations with patient rights.*

**Keywords:** *informed consent; medical law; bioethics.*

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## **Introduction**

In this presentation, we will analyze the concept of informed consent from a bioethical and legal perspective, highlighting its dual role as a decision-making process and administrative tool in the context of medical practice and human subject research. Informed consent is examined as a distinct legal institution in the process of formation within international medical law, created to ensure respect for the rights of patients and research subjects, especially in situations involving potential restrictions on individual freedoms (Sandu, 2025).

Within this presentation, we will make a series of statements with the purpose of clarifying the legal nature of informed consent as a unilateral act specific to the medical field, distinct from a simple condition of validity of the legal act as consent is viewed in civil law. The potential tension between the decision-making role and the administrative role of informed consent in medical practice is highlighted.

## **Informed consent - definition**

Informed consent is a process in which a participant voluntarily confirms their willingness to participate in a particular action (mostly medical or scientific), after having been informed of all aspects relevant to their decision. It encompasses comprehension of disclosed information, voluntary choice, and explicit authorization, ensuring ethical conduct in research, medical procedures, and data collection.

From the perspective of legal relations in healthcare, informed consent represents the central instrument in protecting the rights of patients and participants in biomedical research.

## **Informed consent as administrative act**

Informed consent, as an administrative act, is a formalized procedure within institutional frameworks that documents a subject's voluntary agreement to participate in a study or undergo a medical or psychological procedure. It involves standardized protocols for information disclosure, verification of understanding, and official documentation of consent, adhering to regulatory requirements and institutional policies to ensure ethical compliance and legal protection.

## **Legal and moral landmarks on informed consent in the context of international human rights law**

We will also briefly analyze alternative forms of consent used when obtaining standard informed consent is not possible, as well as their limitations. We examined the relationship between patient autonomy as a central ethical value and the practice of obtaining informed consent, in the context of fundamental human rights.

We will make a distinction between the concepts of freedom and autonomy, fundamental for interpreting and applying legal norms in the medical sphere. The study offers a comprehensive analysis of informed consent, highlighting its legal and ethical complexity in the context of contemporary medicine and human subject research, while also proposing directions for improving the legislative framework and current practices (Sandu, 2025).

### **Axiological and normative foundations of informed consent**

Informed consent constitutes the axiological and normative foundation for the protection of human rights in medical and biomedical research contexts, evolving from a simple notion of civil law to an essential instrument in human rights protection.

Examining the philosophical origins of the concept of autonomy, we can trace a line from Kantian thought (Kant, 1972), which postulates autonomy as the source of human dignity, to contemporary interpretations that incorporate elements from post-Kantian and utilitarian theories. We can highlight the transition from a transcendental vision of autonomy to one that takes into account contextual factors such as emotions, personal values, and social circumstances in the decision-making process.

Informed consent is presented as a legal expression of autonomy, representing a unilateral act through which the patient or research subject expresses agreement for a medical intervention or participation in a study. This legal instrument goes beyond mere procedural formality, constituting a complex process of communication and deliberation between patient and professional.

We pay particular attention to the evolution of the concept of informed consent in international law as well as in European law, and particularly in that of the European Union. We have analyzed key legal instruments from the international human rights protection system, such as the United Nations Charter (1945) and the Universal Declaration of Human Rights (1948), the International Covenant on Civil and Political Rights and

the International Covenant on Economic, Social and Cultural Rights (both from 1966), the UN Convention against Torture (1984) or the UN Convention on the Rights of Persons with Disabilities (2006), the Declaration of Helsinki (WMA,1964).

### **The ethical principles present in the Declaration of Helsinki**

**Respect for subjects:** This means that their participation in research must be voluntary, based on informed consent. The information that the subject must receive includes the purpose and procedures of the research, the risks and benefits involved - both for themselves and for scientific evolution in general. Possible states of discomfort that could arise, both during the research and in the subsequent period, must also be presented. The institutional affiliation of researchers and the funding sources of the research project must also be presented to participants, rather for ethical reasons - avoiding conflicts of interest than protecting human rights. The person's right to refuse to participate in research or to withdraw from it at any time must be clearly presented to the subject.

**Benefits and risks involved in research:** For research involving human subjects to be ethically acceptable, it must have significant potential health benefits - we are talking here about both the health of research participants and especially potential future beneficiaries of research results, and the risks assumed by participants should be minimized and justified by the anticipated benefits.

**Ethical review:** Studies must receive approval from an independent ethics committee, which ensures during the evaluation that ethical standards are respected and subjects' rights are protected.

**Subject safety:** The priority of subjects' well-being and safety throughout the research is essential, with researchers having the obligation to intervene if adverse effects are reported, eliminating the research participant who manifests these adverse effects, or even immediately stopping the entire research if the situation requires it.

**Honesty in publishing and disseminating results:** Whether positive or negative, results should not be hidden from the scientific community. These should be published to contribute to the advancement of medical knowledge and to ensure transparency.

## **Other ethical declarations of principles regarding the informed consent**

Informed consent also represents an important element for protecting individual autonomy and the right to life and dignity in the Council of Europe system, highlighted in normative acts such as the Oviedo Convention and also in the protocols to the European Convention on Human Rights and, implicitly, in particular decisions of the European Court of Human Rights.

### **The Oviedo convention**

For exemplification, we present some aspects regarding informed consent, contained in the Oviedo Convention. Adopted in 1997, this represents a fundamental document in protecting human rights and human dignity in the biomedical field and human subject research. The key principles of the convention include:

1. The primacy of the human being over scientific or societal interests.
2. Equitable access to quality medical care.
3. The obligation of informed and free consent for medical interventions and research.
4. Special protection of vulnerable persons (minors, persons with mental disabilities).
5. Prohibition of discrimination based on genetic heritage.
6. Prohibition of using the human body or organs for profit.

The Convention stipulates that any medical intervention requires free and informed consent, expressed in writing. The information provided must be complete, correct, and adapted to the person's level of understanding. Participation in research must be voluntary, and research projects must be approved by ethics committees.

The document introduces the concept of informed consent as a distinct legal act, designed to protect the rights of patients and research participants. The Convention also addresses specific aspects such as:

- Prohibition of creating human embryos for experiments.
- Limiting organ removal from persons incapable of consenting.
- Regulation of post-mortem organ donation.

### **Reglementation of informed consent within the European union**

At the European Union level, the Charter of Fundamental Rights of the European Union (2012) was presented, from the perspective of how it has contributed to consolidating informed consent as an instrument for

protecting human rights in the medical context. The term consent has a singular presence in the Charter, in the context of Art.3. paragraph 2, letter a) of Title 1 - Dignity. The term consent appears in the context of the discussion on the right to personal integrity, imperatively establishing the free and informed consent of the person concerned. The idea of consent appears in the contexts of medicine and biology.

### **Importance of voluntary nature of informed consent**

We highlight the importance of the voluntary nature of informed consent, emphasizing the need for the absence of any form of coercion or unjustified influence. We make a comparison with classic consent in civil law, showing that in the case of informed consent, the burden of proof regarding the validity of consent falls on the medical professional or researcher.

Informed consent has evolved from a simple concept of civil law to a particular type of complex legal act, specific to the medical field and biomedical research. This evolution of the concept of informed consent reflects a fundamental change in approaching the relationship between patient/subject and medical professional/researcher, replacing the paternalistic model with one centered on individual autonomy and self-determination.

### **Health and legal relations in healthcare**

Health is defined in the legal context as a fundamental right of the human being, protected by both domestic and international legislation. The World Health Organization's definition extends the concept of health beyond the mere absence of disease, including physical, mental, social, and spiritual well-being.

The medical legal relationship can be analyzed as a complex social relationship, regulated by legal norms, in which the involved parties - doctor and patient - are holders of reciprocal rights and obligations. A tension can be highlighted between the contractualist perspective on the doctor-patient relationship and the perspective that views this relationship as arising only from the legal obligation to provide treatment.

The medical legal relationship contains both subjective rights and correlative obligations for both parties involved, hence the contractualist nature - which, however, contrasts on one hand with the unilateral character of the legal act of informed consent and, on the other hand, with the lack of the doctor's obligation to treat the patient in the manner desired by them but

in accordance with good professional standards and legal obligations. Obtaining informed consent is, on the other hand, a process and not just a legal act, the latter representing only the unilateral consecration of the result of the information-deliberation process.

Informed consent is presented as an essential legal instrument in protecting patient rights, going beyond the simple function of exonerating the doctor from liability and representing a guarantee of respecting the patient's autonomy and right to self-determination. There are various forms of autonomy - rational, expressive, relational - and each of these represents a way in which they influence the process of obtaining informed consent.

One of the most important challenges in implementing informed consent is the need to adapt information to the patient's level of understanding and the medical professional's effort to ensure that the patient makes a truly informed and voluntary decision. In this context, we highlight the importance of informed consent as a continuous process, not just as a punctual administrative act.

The issue of medical liability can be approached by analyzing the difference between the obligation of result and that of diligence in the medical act, arguing that, in general, the doctor's obligation is one of means, not of result, with the exception of specific situations such as cosmetic surgery. This has concrete implications for the evaluation of medical malpractice and professional fault.

### **Informed consent - contract or unilateral act?**

Critically analyzing the contractualist approach to the doctor-patient relationship, we argue that, although there are contractual elements, informed consent transcends this perspective. We emphasize its nature as a unilateral legal act, which forms the basis for establishing a contractual-type relationship, without being confused with it. This distinction is essential for the correct understanding of the legal nature of informed consent and its practical implications.

### **The diligence obligation vs result obligation**

The issue of medical liability can be approached by analyzing the difference between the obligation of result and that of diligence in the medical act, arguing that, in general, the doctor's obligation is one of means, not of result, with the exception of specific situations such as cosmetic surgery. This has concrete implications for the evaluation of medical malpractice and professional fault.

### **Informed consent as unilateral act**

Informed consent represents a unilateral legal act, through which the subject expresses informed agreement for interventions that may affect their bodily integrity or even life, for the purpose of realizing a right considered superior, such as the right to health. This conceptualization extends the applicability of informed consent beyond the medical sphere, towards other areas where fundamental rights such as dignity or privacy are involved.

### **Patient's right to information**

Special attention must be given to the patient's right to information and the doctor's correlative obligation to inform, outlining the limits of this right, as well as situations where the doctor may withhold certain information in the therapeutic interest of the patient. The importance of effective and adapted communication between doctor and patient must be emphasized to ensure truly informed consent.

### **Jurisprudence of the European Court of Human Rights**

Through the analysis of relevant jurisprudence of the European Court of Human Rights regarding informed consent and the right to privacy in the medical context, significant cases can be highlighted that have contributed to clarifying and developing the doctrine in this field, marking the complexity of legal relations in healthcare and the crucial importance of informed consent as an instrument for protecting patient rights. This justifies the need for a balanced approach that takes into account both patient autonomy and the professional obligations of the doctor and the public interest in health.

### **Few conclusions**

A fundamental finding of the study is the transformation of informed consent into a distinct legal-social practice, derived from classic consent in civil law, but adapted to the specifics of relationships in the medical field and human subject research. This evolution reflects a growing recognition of the importance of individual autonomy and the need to balance power relationships between professionals and the beneficiaries of their services.

We highlight the importance of understanding informed consent not only as an expression of rational autonomy but also as a manifestation of the subject's expressive and relational autonomy. This nuanced approach

recognizes the complexity of the decision-making process in the medical context, taking into account factors such as personal values, and the patient's social and cultural context.

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