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Legal and Moral Landmarks on Informed Consent in the Context of International Human Rights Law

- summary -

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Introduction

In this paper, we have analyzed 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.

The research methodology we have adopted includes monographic, comparative, and jurisprudential analysis, with emphasis on the practice of the European Court of Human Rights and relevant national and international legislation. The study addresses the historical evolution of the concept, its particularities in relation to general consent in civil law, and its ethical and legal implications.

Within this work, we have made a series of contributions in 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.

We have also analyzed 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.

In this paper, we have also addressed the issue of medical fault from a contractualist perspective, correlating it with the patient's right to information and potential vices of consent. The importance of informed consent as a multidimensional instrument for legal protection of the right to life and privacy has been emphasized, both in international and national law.

Within the paper, we 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.

A significant contribution of the paper we see it consisting in the parallel analysis of the evolution of informed consent in the medical field and in consumer law. A common trend is identified in protecting individual rights in relation to more powerful legal entities, reflecting a transition from

the model of contractual autonomy to a more nuanced model that recognizes the inherent power imbalances in certain legal relationships.

Chapter I. 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, 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.

In the bioethical context, we emphasize the importance of the principle of respect for individual autonomy, corroborated with other fundamental principles such as beneficence, non-maleficence, and distributive justice. This multidimensional approach reflects the complexity of decisions in the medical field and biomedical research. Freedom is conceptualized as the absence of external constraints, while autonomy implies the capacity for rational decision-making and assuming responsibility for decisions made.

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 have paid 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 or the UN Convention on the Rights of Persons with Disabilities, the Declaration of Helsinki. To exemplify the ethical and legal requirements regarding informed consent in biomedical practice, we present some

such requests, as they result from the Helsinki Declaration (from 1964) and also from the updates brought by the World Health Organization conferences from 1964 to 2024.

Among the ethical principles present in this Declaration, we enumerate:

- 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.

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 analyzed in the paper.

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.

At the European Union level, the Charter of Fundamental Rights of the European Union 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.

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.

We highlight in the paper 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.

In the chapter, we also explore the issue of consent in special situations, such as medical emergencies or the participation of vulnerable persons in research. We emphasize the need for a balance between respecting individual rights and medical or scientific imperatives, highlighting the complexity of these situations from a legal and ethical perspective.

Regarding state legislations, we comparatively analyzed approaches from different legal systems, focusing on France, Great Britain, and the Republic of Moldova. We note the differences in conceptualizing and implementing informed consent, reflecting the distinct legal and cultural traditions of these countries.

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.

The importance of continuously adapting the legal and ethical framework of informed consent to contemporary challenges, including those brought by new medical and research technologies, needs to be emphasized. The need for a balance between protecting individual rights and facilitating medical and scientific progress must be highlighted, emphasizing the crucial role of informed consent in ensuring this balance.

Chapter II. Health and Legal Relations in Healthcare

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.

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. This holistic approach has significant implications for how legal relations in healthcare are conceptualized and regulated.

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. Although there are contractual elements in the provision of medical services, medical activity is essentially a professional one, regulated by both the Civil Code and specific legislation. 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.

Special attention is given to the concept of inviolability of the human body and the individual's right to dispose of their own body. The limits of this right are analyzed, as well as exceptions allowed for medical or religious purposes. In this context, we have also addressed controversial aspects such as cosmetic surgery, eugenic practices, and genetic editing, emphasizing the need for clear regulations in these emerging fields.

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.

The historical analysis of the evolution of the concept of informed consent starts from American jurisprudence at the beginning of the 20th century, culminating with the Nuremberg Code and subsequent developments. Current bioethics and biolaw highlight the transition from a paternalistic approach to the medical relationship to one centered on patient autonomy and respect for their fundamental rights.

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.

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.

Addressing aspects related to the right to privacy and personal dignity in the medical context, it is necessary to discuss issues related to the confidentiality of medical data and the limits within which they can be disclosed, as well as situations where public interest may justify an interference in the patient's private life, such as in cases of threats to public health.

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.

We advocate for a nuanced understanding of informed consent, which goes beyond mere administrative formality and becomes a dynamic process, adapted to the individual needs and capacities of patients, as well as for the importance of continuous education of both medical staff and patients, to ensure an effective implementation of the principles of informed consent in medical practice.

The need for continuous adaptation of the legal and ethical framework to developments in the medical and biotechnological field must be highlighted, to ensure adequate protection of patient rights in the face of new challenges and ethical dilemmas. Future developments in the field of medical law should focus on finding a balance between patient autonomy, professional responsibility of the doctor, and the public interest in health.

Chapter III Informed Consent in Non-Therapeutic Contexts

We conducted an analysis of informed consent in non-therapeutic contexts by examining the implementation of this concept in various medical institutions and extending the discussion to other areas where similar principles of informed consent apply.

The analysis of informed consent forms used in Romanian medical institutions highlighted a series of inconsistencies and problems in the implementation of this legal instrument, revealing a predominant tendency towards an administrative-bureaucratic approach, with emphasis on protecting the medical institution and medical personnel against potential litigation, to the detriment of the patient's real interest. Many forms reflect a paternalistic attitude, asking patients to grant almost unlimited trust to the doctor, sometimes even beyond the limits of expressed consent.

In the field of palliative care, we identified specific problems related to the inclusion of mandatory provisions regarding do-not-resuscitate (DNR) orders in the service contract, raising ethical and legal questions about respecting the patient's right to self-determination.

The extension of the informed consent model in non-therapeutic contexts reflects a broader trend of medicalization of social life and formalization of human relationships. This phenomenon is also manifested in the regulation of interpersonal relationships, such as in the sphere of sexual life, raising questions about the limits of applicability of the concept of informed consent outside the medical field.

In the sphere of biomedical research, informed consent emerges as an essential instrument for protecting the rights of research participants. There is a trend towards international standardization of ethical and legal practices associated with human subject research, with emphasis on voluntary participation, complete information, and protection of vulnerable groups.

We can argue for the emergence of a "research law" as a specialized branch, emphasizing the need for specific regulations, especially regarding ensuring real understanding of information by participants. In this context, research ethics becomes an integral part of this law, alongside elements of intellectual property protection and scientific responsibility.

Rapid technological evolution, especially in the field of Artificial Intelligence, generates new challenges regarding the protection of personal data and respect for the right to privacy. Although the General Data Protection Regulation (GDPR) provides a general framework, we consider that it needs to be adapted and expanded to face new technological realities.

In the context of GDPR, it is argued that, although the term "informed consent" is not explicitly used, the principles underlying it are reflected in the requirements for valid consent. We wish to emphasize the need for a more nuanced and comprehensive approach to consent, especially regarding digital identity and protection against its manipulation through emerging technologies.

We advocate for a more nuanced approach to informed consent, which takes into account the increasing complexity of data processing through Artificial Intelligence systems and the potential impact on individual privacy and identity. We suggest adopting an informed consent model analogous to that in the medical field, adapted to the specifics of data protection and the use of emerging technologies.

We formulate a *de lege ferenda* proposal aimed at modifying and supplementing Law 95/2006 on healthcare reform. The main proposed modifications include:

1. Establishing a mandatory reflection period between informing the patient and obtaining consent.

2. Separating therapeutic consent from other forms of consent requested from the patient.

3. Requesting specific consent for each therapeutic act, except in emergency situations.

These modifications are justified by the need to ensure an informed and voluntary decision from the patient, avoid psychological and emotional pressures, and prevent misinterpretations of the limits of consent. The legislative proposal aims to align with the most current international practices and improve doctor-patient communication, without compromising the efficiency of procedures in emergency situations.

As a concluding note, we emphasize that, in the context of voluntary and partial renunciation of exercising certain rights in favor of technological or social benefits, it is essential that this renunciation is based on adequate informed consent. The responsibility for informing and proving this should lie with the entity in whose favor consent is given, thus ensuring real protection of the individual's fundamental rights in an increasingly digitalized and interconnected society.

General conclusions

This paper provides an in-depth analysis of the concept of informed consent, highlighting its evolution from a simple procedural formality to a complex instrument for protecting human rights, with primary applicability in the medical field and biomedical research. We emphasize the dual nature

of informed consent, both as a process of information and decision-making, and as an administrative instrument with legal value.

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.

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.

A significant contribution of the paper consists in the critical analysis of practices for obtaining informed consent in medical institutions in Romania. Discrepancies were identified between international standards and local practice, highlighting the tendency to treat informed consent as an instrument for protecting the doctor against malpractice accusations, rather than as a mechanism for guaranteeing patient rights.

The paper proposes a reconceptualization of informed consent in the context of contemporary technological developments, especially in the digital era and artificial intelligence. It emphasizes the need to adapt consent-obtaining practices to new technological and social realities, including in areas such as telemedicine and the use of biobanks.

An innovative aspect of the research is the proposal of a dynamic consent model, adapted to the current technological context. This model would allow better protection of subjects, especially in situations where there is an overlap between participation in research and personal data protection.

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.

An important theoretical contribution of the paper consists in clarifying the relationship between autonomy as a central ethical value in medical practice and informed consent as an instrument for realizing this value, and how informed consent serves to protect fundamental rights such as the

right to life, health, and bodily integrity, while analyzing the limits and limitations of these rights in the context of medical care and research.

The paper also brings into discussion the issue of consent in special situations, such as palliative care or genetic therapies. It emphasizes the need for a nuanced approach to consent in these contexts, taking into account aspects such as therapeutic obstinacy, do-not-resuscitate orders, or the long-term implications of genetic interventions.

A critical aspect identified in the paper is the tendency towards excessive formalization of informed consent, which risks reducing it to a simple administrative procedure, to the detriment of its fundamental purpose of protecting patient rights, arguing for the need to maintain a balance between the formal and substantial aspects of informed consent.

The *de lege ferenda* proposal formulated in the paper aims to modify and supplement Law 95/2006 on healthcare reform. The main proposed modifications include establishing a mandatory reflection period between informing the patient and obtaining consent, separating therapeutic consent from other forms of consent, and replacing generic consent with specific consent for each therapeutic action. These proposals aim to improve doctor-patient communication and align national practices with international standards.

We emphasize the importance of the jurisprudence of the European Court of Human Rights in shaping the concept of informed consent in the European legal space and highlight the Court's tendency to extensively interpret the European Convention on Human Rights, framing aspects related to informed consent within the sphere of privacy protection.

In the context of technological and scientific developments, the paper draws attention to the need to adapt the concept of informed consent to new realities. We discuss the specific challenges brought by personalized medicine, genetic therapies, and the use of artificial intelligence in medicine, emphasizing the importance of addressing aspects related to scientific uncertainty and the long-term implications of advanced medical interventions.

The central conclusion of the paper underlines the need to balance individual autonomy with public interest in areas where an individual voluntarily and informedly consents to diminishing the exercise of a right in favor of realizing a right considered superior. Informed consent is presented as an essential legal instrument in this balancing process, meant to symmetrize power relationships between the involved parties.

Finally, we propose a series of future research directions, with emphasis on studying the impact of Artificial Intelligence on the process of obtaining informed consent in various medical and

research contexts. This proposal reflects the recognition of the continuous need to adapt the conceptual and practical framework of informed consent to ongoing technological and social developments.

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