

# Informed Consent for Treatment, as an Instrument for Protecting the Right to Dignity

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## **Abstract**

*Informed consent appears in bioethics and medical law doctrine both as a process of informing the patient and making a decision regarding the therapeutic approach or the research they will be part of, and as an administrative tool - form or set of forms - with the value of a unilateral legal act to justify the patient's agreement and exculpate the doctor for potential harm.*

**Study objectives:** *Identifying discrepancies regarding the procedures for obtaining informed consent in Romania, compared to international practice in the field.* **Research methods:** *The specifics of informed consent for therapy in various Romanian medical institutions were analyzed from the perspective of legal sociology and human rights theory.* **Results:** *Consent forms represent more of an administrative act rather than the result of implementing a process of informing the patient and deliberation on their part.* **Implications:** *Informed consent is a particular form of consent, by which the subject consents to an intervention upon themselves, which temporarily restricts the exercise of a right considered by the individual to have a higher value.*

**Keywords:** *informed consent; patient rights; bioethics; medical law; human dignity.*

**JEL Classification:** K32, K33

## **1. Introduction**

The restriction of certain patient rights, such as bodily integrity, for example, is allowed to the doctor during the medical act through a particular legal act called ***informed consent***, given for the purpose of carrying out the treatment. The partial restriction of the right to bodily integrity represents an act of disposition over the patient's own body, which will subsequently lead to the realization of a right considered to have superior value - the right to health. The individual can refuse to consent or can limit their consent when they consider that the realization of another right considered by them to have a superior value - the right to dignity, for example - is affected.

We will clarify during the article that, as it appears in bioethics and in the doctrine related to medical law, informed consent - both as a process of informing the patient and making a decision regarding the therapeutic approach, and as an administrative tool - form or set of forms - with the value of a unilateral legal act to justify and prove the patient's agreement and to exculpate the doctor for any harm to the patient that occurs during the therapeutic process and which is not due to the doctor's fault or ignorance, risks about which the patient has been notified and to which they have consented. Also, informed consent covers risks that the doctor was not and could not have been aware of - and, as such, did not communicate to the patient - therefore, informed consent forms also include risks that cannot normally be foreseen.

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We will aim to identify a series of discrepancies regarding the procedures for obtaining informed consent in Romania, compared to international practice in the field.

Among the proposed solutions, we will find a series of *de lege ferenda* proposals aimed at obliging medical service providers to fulfill a number of essential requirements regarding the consent form.

## 2. Informed consent as a legal and administrative act

The specific features of informed consent for therapy in various Romanian medical institutions were analyzed from the perspective of legal sociology and human rights theory. The specific nature of informed consent as a unilateral legal act was also analyzed.

From a legal perspective, informed consent represents an instrument for guaranteeing the respect of the individual - the patient's - rights or the rights of other categories of individuals to whom informed consent applies in relation to individuals, especially professionals, or a group of individuals or even organizations acting upon the person who gives the consent, in a manner in which the lack of consent could be considered a restriction of certain freedoms or rights, which can only be justified by this agreement of will. Informed consent represents a legal-administrative instrument with the role of ensuring the respect of patients' rights, both in therapeutic practice and in research involving human subjects.

French doctrine, after the Teyssier case, contests the classical understanding of the medical relationship in the form of a contract, showing that in medical law, since the right to possession of one's own body is a special right, greater importance should be given to consent which, to be valid, the doctor must ensure that the patient has all the necessary information to decide with full knowledge of the facts, in other words, the consent must be informed. The doctor's obligation to inform the patient is conferred by law, while the patient's informed consent gives the doctor the right to act on the patient's body. As such, the medical act represents a bilateral relationship that gives rise to rights and obligations, but these rights and obligations are born, in the case of the doctor, by virtue of the law and the authorization given by the patient, while for the patient the right to receive treatment is born by virtue of the law, and the obligation to accept the treatment, which seems to be instituted by informed consent, is extinguished at any time at the unilateral wish of the patient<sup>2</sup>.

The special contractual nature of informed consent is also supported by Gabriel Năsui<sup>3</sup>, who points out that in addition to the contractual nature of liability for medical malpractice, the doctor also has delictual liability when the obligation to treat arises by virtue of the law.

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<sup>2</sup> Mihăilă, Camelia. "Informed Consent in Medical Law in the Romanian Legal System. A Comparative Law Perspective." *Journal of Intercultural Management and Ethics* 5, no. 2 (June 2022): 37-43. <https://doi.org/10.35478/jime.2022.2.05>.

<sup>3</sup> Năsui, Gabriel Adrian, *Malpraxisul medical. Particularitățile răspunderii civile medicale. Jurisprudență internă relevantă. Malpraxisul profesiilor liberale* (3<sup>rd</sup> edn.). Bucharest: Universul Juridic, 2024.

### 2.1. From consent in civil law to informed consent

The concept of consent has its origins in Roman Civil Law, representing a condition for the validity of legal acts. It has the same meaning in civil law, both in Romanian law and in the law of other states. In civil law, consent appears both in the case of unilateral acts and especially in bilateral ones - in contracts. In consumer law, although less formalized, consent has rather the role of adhering to the commercial policies of the merchant, being necessary in the acquisition of the product or service. Commercial law includes the specific obligation for the merchant to inform consumers. There is an opinion in the literature that informed consent in the medical field is a particular form of commercial consent in the relationship between the doctor and the patient. This relationship is assimilated to a professional-client relationship, having a contractual nature<sup>4</sup>.

In the medical field, the concept of informed consent has developed as a particular form of patient protection. It has also expanded to other caring professions, reflecting a trend of the medicalization of social life.

We consider informed consent a particular legal institution, as in form it represents a unilateral act, but it involves the relationship between two people, sometimes interpreted in a contractual sense. However, the doctor's obligations derive rather from the effect of the law, and his liability is more of a delictual nature. In accordance with the law, the doctor has the obligation to inform the patient, correctly, completely and in a manner understandable to him, that is, in a manner similar to consumer law, but the document does not take the form of a medical contract similar to the one in French law, but the form of a unilateral act - informed consent materialized through the Informed Consent Form and a specific procedure for obtaining it.

This concept represents a legal expression of the individual's right of possession and disposition over his own body. Although it does not directly entail medical liability - medical malpractice being established based on the law and specific practice guidelines and not on consent - informed consent is often used as a protective method for doctors against malpractice allegations.

For it to be valid, informed consent must be based on complete and accurate information provided to the patient about his or her health condition, the proposed treatment and possible outcomes, and the medical intervention must be performed in accordance with professional standards and in good faith, as much as possible within the limits accepted by the patient within the framework of informed consent.

### 2.2. Legal context. Informed consent in accordance with the Law on Patients' Rights in Romania

Law on Patients' Rights No. 46/2003<sup>5</sup> speaks, in several articles, about the patient's right to dignity, protected through informed consent. The patient's informed

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<sup>4</sup> Rowe, K., Moodley, K. Patients as consumers of health care in South Africa: the ethical and legal implications. *BMC Medical Ethics* 14, 15 (2013). <https://doi.org/10.1186/1472-6939-14-15>.

<sup>5</sup> Legea nr. 46/2003 privind drepturile pacientului, *Monitorul Oficial al României*, Partea I, nr. 51 din 29 ianuarie 2003 [Law no. 46/2003 regarding patient rights. Official Gazette of Romania, Part I, no. 51 (January 29, 2003)].

consent represents an essential aspect addressed in this law, within several articles:

- Article 6 of the Law mentions the right to information - specifically, it states that the patient has the right to be informed about their health condition, proposed medical interventions, potential risks of each procedure, existing alternatives to the proposed procedures, as well as the consequences of not undergoing treatment and not following medical recommendations. Correlated with the right to information, the patient also has the right to refuse information - a right stipulated in Articles 7 and 9 - in which case they can designate another person to be informed in their place and who can make decisions for and with them. The information must be provided to the patient or their relatives in clear language, reducing as much as possible the specialized terminology that the patient might not easily understand, without, however, eliminating essential information;

- In the case of patients who do not know Romanian, the information must be provided in a language they understand, if possible, their mother tongue, in accordance with Article 8. When the patient is deaf or mute, sign language can be used with the help of an interpreter.

- In the case of medical interventions, the patient has the right to refuse or stop the respective intervention as well as preoperative procedures, or treatment, assuming responsibility for their decision in written form, in accordance with Article 13;

- In emergency situations, the consent of the patient or legal representative is no longer necessary, in accordance with Article 15, consent being presumed especially in the case of life-saving therapies or interventions. When the patient cannot directly express their will, it is understood by the medical staff, based on the patient's previous expressions of will, according to Article 14, in which case the consent of the legal representative is no longer necessary, in accordance with Article 15. Presumed consent based on the patient's previous expressions of will can only be valid when the medical staff has personal knowledge of these expressions of will, and not when they are brought to their attention by a third party. In the latter case, the patient's intention to be treated is presumed;

- In cases where consent must be given by a parent or legal guardian, due to the patient's minor status or incapacity, the latter must still be consulted and their wishes should be taken into account in the medical decision (Art. 16). An arbitration committee is necessary when, despite the patient's agreement, the legal representative refuses to give consent (Art. 17);

- In the case of collecting biological products, through harvesting, storage, and use, consent is required according to Art. 17. However, the law does not specify the patient's obligation to consent to how biological products are used after collection and potential diagnosis (Art. 18). Their destruction is somewhat presumed. In practice, however, there have been cases where biological products were used in subsequent research, especially of a genetic nature, and consent for this use was introduced in the informed consent form, illegitimately in our view - a situation we will discuss later in this paper;

- For the patient's participation in clinical medical education, Art. 19 requires the doctor to obtain informed consent from the patient, along with consent for participation in research. We consider it necessary to separate the three consents - for treatment, for participation in research, and for participation in clinical medical education - for a better

understanding by the patient of the areas and limits for which they give consent. Regarding participation in research, two types of research are distinguished: clinical experiments, which in practice require appropriate particularized informed consent, and usual clinical research, conducted based on the interaction between patients and treating physicians, which is usually included in the consent form for the therapeutic act. As we will show later, we consider this latter practice to be likely to vitiate consent through confusion between the two areas for which the patient is asked to consent;

- It is forbidden to photograph or film the patient without their express consent, except for images necessary in the diagnostic process (Art. 20);

- For each specific medical intervention in personalized medicine, the patient's informed consent is mandatory, according to Art. 36 para. 2. However, in many medical institutions, informed consent once given is valid for multiple procedures and interventions, as we will present in this paper. Extending this obligation from the field of personalized medicine to all medical practices applied to the same patient and, respectively, in the case of chronic patients, renewing informed consent at certain intervals - we believe can lead to better respect for the patient's rights to autonomy and dignity.

### 2.3. Informed consent in French law

In French medical law, informed consent represents a fundamental principle originating, like Romanian law, from respect for patient autonomy and their right to self-determination. This concept has evolved significantly in recent decades, being consolidated through legislation<sup>6</sup> and jurisprudence. In the previously cited Law on Patients' Rights and the Quality of the Health System, it is stipulated that for any medical act and treatment, the patient's free and informed consent is mandatory, except in emergency situations or impossibility. The information that must be given to the patient mandatorily, in a complete and comprehensible manner, relates to details about the diagnosis, the nature of the proposed intervention, associated risks, therapeutic alternatives, and the consequences of refusal. In accordance with jurisprudence, it has been established that the information must be adapted to the patient's capacity for understanding, taking into account factors such as age, education, and psychological state.

The right not to know reflects a particular aspect of patient autonomy in French law. French bioethical and medical law literature refers to the need to adapt legislation regarding consent to the challenges that arise with personalized medicine and the use of Artificial Intelligence in medicine, as well as to new technological and ethical realities<sup>7</sup>.

In conclusion, French medical law places particular importance on informed consent, seen as an expression of respect for human dignity and patient autonomy, continuously adapting to social and technological developments.

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<sup>6</sup> Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé. [Law No. 2002-303 of March 4, 2002 on patients' rights and the quality of the health system]. NOR: MESX0100092L. Accessed on 2 November 2024. <https://www.legifrance.gouv.fr/eli/loi/2002/3/4/MESX0100092L/jo/texte>.

<sup>7</sup> Paricard, S. "Le consentement à l'acte médical." [Consent to medical treatment]. *Gynécologie Obstétrique Fertilité & Sénologie* 51, no. 4 (2023): 212-216. <https://doi.org/10.1016/j.gofs.2023.02.001>.

## 2.4. Informed consent in British law

Informed consent in British medical law has evolved significantly in recent years, especially after the Montgomery case<sup>8</sup> in 2015, which marked a fundamental shift in the standard of disclosure of medical risks. In accordance with British doctrine, there has been a transition from the "reasonable physician" standard to that of the "reasonable patient," which means that doctors are obliged to disclose information that a reasonable patient would consider significant for making an informed decision about their treatment.

The main aspects of informed consent in Great Britain include: the patient's competence to make a voluntary decision, adequate disclosure of relevant information, including risks and alternatives, the patient's understanding of the information provided, and the patient's voluntary agreement to treatment. We are therefore talking about a patient-centered approach aimed at promoting high-quality decision-making in healthcare, taking into account patients' values and preferences<sup>9</sup>.

## 2.5. Alternatives to informed consent

In the biomedical sphere, especially in research, a series of alternatives to informed consent are used that are considered legally and administratively acceptable.

*Delegated consent* is legally used mainly for minors<sup>10</sup> or adults incapable of consenting due to their health condition. A guardian or curator makes the decision on behalf of the subject. For children over 14 years old, their assent is also requested, although their assent is not valid without the guardian's consent. In certain contexts, depending on the patient's health condition, informed consent is requested from relatives without them being legal guardians, in which case we speak of delegated consent.

*Broad consent* is requested for the use of data or biological samples collected for diagnostic purposes in unspecified future research<sup>11</sup>. This is not a complete informed consent, lacking a series of specific information. We find such a form of broad consent in many informed consent forms available on the websites of medical institutions, usually being automatically requested upon patient admission, along with informed consent for treatment. This can lead, in our opinion, as we will discuss later, to confusion in the patient's mind regarding the type of consent they are about to give and its purpose.

*Dynamic consent* allows subjects to continuously inform themselves about the use of their data or biological samples through updated online platforms, offering platform users the possibility to withdraw the broad consent previously given. A particular form of dynamic consent, combined with broad consent, is called meta-

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<sup>8</sup> Saw Ying Chan et al., "Montgomery and Informed Consent: Where Are We Now?," British Medical Journal 357 (2017): j2224, <https://www.bmj.com/content/357/bmj.j2224>.

<sup>9</sup> Alasdair Maclean, "Autonomy, Informed Consent and Medical Law: A Relational Challenge," Cambridge Law, Medicine and Ethics, Series Number 8 (Cambridge: Cambridge University Press, 2009), pp.149-190

<sup>10</sup> Marshall B. Kapp, "Children's Assent for Participation in Pediatric Research Protocols: Assessing National Practice," Clinical Pediatrics 22, no. 4 (April 1983): 275-278, <https://doi.org/10.1177/000992288302200406>.

<sup>11</sup> Thomas Ploug and Søren Holm, "Going Beyond the False Dichotomy of Broad or Specific Consent: A Meta-Perspective on Participant Choice in Research Using Human Tissue," The American Journal of Bioethics 15, no. 9 (2015): 44-46, <https://doi.org/10.1080/15265161.2015.1062178>.

consent. Romanian legislation does not currently provide for either the form of dynamic consent or meta-consent.

*Generic consent generally* refers to the subject's agreement to participate in research during the therapeutic process or in medical education, without altering the therapeutic protocol<sup>12</sup>. We believe that this form of consent is not clarified in Romanian legislation, which may lead to confusion that refusing consent for research or participation in medical education affects the subject's right to be treated.

*Presumed consent* occurs when the patient is unable to consent and there are no available relatives, being used especially in emergency situations when the patient is unconscious but is presumed to want their life saved.

*Verbal consent* occurs when the person is illiterate or unable to sign, with a recording being used as evidence of expressing valid consent.

*Partially informed consent* is used mainly in psychological/psychiatric research, only with the approval of an ethics committee that certifies that complete information could affect the research results<sup>13</sup>.

The various forms of consent aim to balance the participants' right to autonomy with therapeutic or research needs, adapting to specific situations and technological evolution.

### 3. Research methodology

**Study objectives:** *Identifying discrepancies regarding the procedures for obtaining informed consent in Romania, compared to international practice in the field.*

**Research methods:** *The specifics of informed consent for therapy in various Romanian medical institutions were analyzed from the perspective of legal sociology and human rights theory.*

The research was conducted based on the analysis of informed consent forms available on the websites of medical units in Romania.

The content analysis method applied to legal acts and texts represents a systematic research technique used to examine documents and interpret them from a legal perspective. In applying this method, the following steps were taken: defining objectives and identifying recurring themes, interpreting legal language, or evaluating legal implications. In selecting the material, informed consent forms available on the websites of public medical units in Romania were considered. As units of analysis, the structural coherence of the document, the balance between therapeutic and research information - as expressed in the form, support for the patient's freedom of choice, respect for human dignity, and mentions regarding data confidentiality were selected, as these result from the documents considered in accordance with the analysis scheme proposed by Beauchamp and Childress<sup>14</sup>. Classification and interpretation criteria for the

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<sup>12</sup> Ana Frunză, Antonio Sandu, "Ethical Acceptability of Using Generic Consent for Secondary Use of Data and Biological Samples in Medical Research," *Acta Bioethica* 23, no. 2 (2017): 289-299, <https://acta.bioethica.uchile.cl/index.php/AB/article/view/47480>.

<sup>13</sup> Onora O'Neill, "Some Limits of Informed Consent," *Journal of Medical Ethics* 29, no. 1 (2003): 4-7, <https://doi.org/10.1136/jme.29.1.4>.

<sup>14</sup> Tom Beauchamp, James F. Childress, *Principles of Biomedical Ethics*, 5<sup>th</sup> ed. (Oxford: Oxford University Press, 2001).

documents were established, ensuring consistency of the analysis. The coding of the analysis was done in accordance with the open coding from Grounded Theory<sup>15</sup>.

During the coding process, categories and criteria for classifying and interpreting the content were created, ensuring consistency of the analysis, identifying and categorizing relevant information which was compared with the standards contained in Romanian and international legislation in the field of informed consent. The information was synthesized and compared with previous results existing in the specialized literature, which will be referenced when presenting the results, in accordance with the model of writing results from Grounded Theory.

### 3.1. Research results

An analysis of informed consent forms available on medical unit websites was conducted, based on a grid formulated from the works of Beauchamp and Childress, as follows:

- ***Analysis of consent forms from Romanian medical institutions.*** A series of overlaps were highlighted between the informed consent for therapy we were analyzing and elements of informed consent for research - especially forms of *broad consent* regarding the use of biological samples collected from the patient in future research. Examining the way of expressing real interest in patient autonomy, a rather paternalistic approach to informed consent was observed, oriented towards using this legal act as a tool for avoiding malpractice accusations.

The grid we considered contained the following elements: procedural vs. formal approach to informed consent; clarity and completeness of information; information about risks, benefits, and therapeutic alternatives; possibility of withdrawing consent; obliging the patient to consent to medical-hospital activities outside the actual therapeutic process: research and didactic elements.

- ***Identified discrepancies compared to international practice.*** From this point of view, correlations were observed in the analyzed consent forms between the actual consent for the therapeutic act, and that for the use of biological materials collected in the diagnostic process, in future research that may possibly contravene some conscientious objections that the patient might have towards these, as well as for patient participation in medical education.

The existence of an express formulation of information stating that refusal of consent for the two aspects related to the therapeutic one does not exclude consent for therapy and therefore does not automatically lead to the patient being deprived of treatment, as in the case of express formulation of informed refusal of treatment, was not noticed in the analyzed forms.

The study highlighted the need for clear separation of different types of consent: for therapy, for collecting and using biological samples in subsequent research, for the presence of students at consultations, or if a single instrument is desired for all three consents, it should include three distinct parts.

The importance of informing patients about the right to refuse certain aspects without affecting access to treatment was emphasized, as well as the need to explicitly

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<sup>15</sup> Antonio Sandu, "Workshop Teoria fundamentată pe date (Grounded Theory). Construcția categoriilor" [Workshop on Grounded Theory. Construction of categories]. (Iași: Lumen Publishing House, 2018).

include this information in the informed consent document.

The analysis revealed the need to improve current practices to ensure better protection of patients' rights and dignity in the context of therapeutic practices, by using informed consent as a legal instrument to protect the rights to health, life, and dignity.

#### **4. Discussions**

The analysis of informed consent documents in the Romanian medical context reveals a series of deficiencies in drafting and structure, suggesting a rather bureaucratic than ethical approach to this process. Although these forms are intended to comply with the Patient Rights Law no. 46/2003<sup>16</sup>, they often present inconsistencies and ambiguities that can compromise the patient's understanding and, implicitly, the validity of consent.

The main problems identified include:

- Lack of internal coherence of the forms, which combine consent for diagnosis with that for treatment, without providing assurance that the patient has been informed and understood that they are being asked to consent to two distinct stages of the medical act;

- The existence of an overlap of different levels of consent, sometimes simultaneously including agreement for diagnosis, treatment, surgical interventions, use of biological samples in future research, and participation in medical education;

- Ambiguity of the forms and implicitly of the consent given, regarding the consequences of informed refusal for certain procedures or uses of patient data. There is no distinct form for informed refusal on the websites of the medical institutions we consulted, and there is no section for complete informed refusal, including treatment, in the forms consulted. There is the possibility of a special informed consent form for discharge on request, which differs from the informed consent signed at admission. In the case of certain medical institutions, the informed consent at admission includes items that need to be checked and about which it is assumed that the patient will consent, both for medical investigations and for the treatment that will be prescribed based on those investigations, about which obviously the patient could not be informed except in the form of a presumed diagnosis at the time of signing, i.e., at admission. Refusal to check these items implies informed refusal of admission and the patient is informed that they will not be admitted - which may lead, in their opinion, to the conclusion of being deprived of treatment;

- Consent for the surgical act asks the patient to leave decisions regarding the operation to the discretion of the operating team, which would be correct for the intraoperative moment but not for the preoperative one;

- Confusion between the legal capacity to sign and the cognitive or physical capacity of the patient to consent, with possible legal implications on the validity of informed consent, therefore requiring delegated consent from relatives.

##### **4.1. Implications for patient rights**

These deficiencies suggest a superficial understanding of the ethical and legal

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<sup>16</sup> Legea nr. 46/2003 [Law no. 46/2003].

principles underlying informed consent, as provided for in Law 46/2003<sup>17</sup>. To improve this process, a revision of consent forms is necessary, focusing on clarity of information, clear separation of different types of consent, and detailed explanation of patient rights, including the right to refuse certain procedures without compromising essential medical care.

Making a brief comparison between the practice of obtaining informed consent in countries such as Great Britain, France, Germany, and Italy, we will try to highlight some discrepancies in the use of informed consent in Romanian medical law and international law<sup>18</sup>.

In Romania, there is a tendency to overlap different levels of consent, simultaneously including agreement for diagnosis, treatment, surgical interventions, use of biological samples in future research, and participation in medical education. This denotes for us the formalism of applying informed consent and the superficiality of understanding it as a form of protection of the right to dignity in our country. Informed consent is seen rather as a tool to exonerate the doctor from liability for medical fault, by extending consent in the form of a generic one that is more of an adhesion act and not a real consent. The method of obtaining this act is influenced by the strong power imbalance between doctor and patient, especially when consent is requested at admission for all procedures that will be performed during hospitalization, and not gradually for each of these.

In international practice from the countries mentioned above, there is a tendency for clear separation of different types of consent. In Great Britain and Germany, consent for treatment is visibly distinct<sup>19</sup> from that for any form of research or use of data for any purpose, including educational purposes<sup>20</sup>.

Regarding the clarity of information and the right of refusal, in Romania there is often a lack of explicit information that refusing certain aspects specified in the consent form does not affect access to treatment.

In international practice, in countries such as France and Italy, it is mandatory to clearly specify, in the very form that establishes informed consent, that refusing certain aspects included in it does not affect the basic treatment. This is considered essential for truly informed consent. However, it has been found that excessive information, manifested for example by doubling the size of the consent form in the case of oncological therapy, does not always lead to better patient information and therefore not to a more efficient process of informing them<sup>21</sup>.

It has also been observed that in Romania, patients are often asked to consent to future procedures, which are unknown to the patient at the time of admission, while in

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<sup>17</sup> Legea nr. 46/2003.

<sup>18</sup> Akkad, Andrea, et al. "Patients' Perceptions of Written Consent: Questionnaire Study." *British Medical Journal* 333, no. 7567 (2006): 528. <https://doi.org/10.1136/bmj.38922.516204.55>.

<sup>19</sup> Tom L. Beauchamp, "Informed consent: its history, meaning, and present challenges." *Cambridge quarterly of healthcare ethics: CQ: the international journal of healthcare ethics committees* vol. 20,4 (2011): 515-23. <https://doi.org/10.1017/S0963180111000259>.

<sup>20</sup> Elwyn, Glyn, et al. "Shared Decision Making: A Model for Clinical Practice." *Journal of General Internal Medicine* 27, no. 10 (2012): 1361-1367. [10.1007/s11606-012-2077-6](https://doi.org/10.1007/s11606-012-2077-6).

<sup>21</sup> Berger, O., Grønberg, B. H., Sand, K., Kaasa, S., & Loge, J. H. "The length of consent documents in oncological trials is doubled in twenty years". *Annals of Oncology*, (2009), 20(2), 379–385. <https://doi.org/10.1093/annonc/mdn623>.

France and Italy, consent is considered a continuous process. For major procedures or significant changes in the treatment plan, new specific consent is obtained. This is also valid in Romania in recent years' practice, but the existing forms are not always updated, and it is not clear to what extent it is applied in all medical institutions<sup>22</sup>.

In Romania, the need for periodic renewal of consent is not explicitly mentioned, although this obligation exists in the Patient Rights Law but not in the documents present on the websites of some medical institutions. However, it has been found that in Germany, renewal of consent at regular intervals (for example, every 6 months) is recommended for certain types of long-term studies or treatments.

Regarding information about diagnostic and screening procedures, this is sometimes limited or ambiguous in Romania, while in France, for example, there is a concern for providing complete and relevant information about screening procedures, such as mammography, with the doctor ensuring that patients understand the benefits and potential risks of these procedures.

We observe that the international trend regarding informed consent is towards a more detailed and transparent approach, in the context of patient-centered medical act, and on creating a therapeutic alliance between doctor and patient.

However, there is another global trend, such as that formulated by Manson and O'Neill, who propose a fundamental reassessment of the concept of informed consent in bioethics and biolaw<sup>23</sup>. They argue that traditional models, based on information transmission and individual autonomy, have become inadequate due to the complexity of contemporary medical practice. The authors have developed an approach based on communication and trust, emphasizing the importance of relational and social context in the consent process. In their view, informed consent should be seen as a dynamic process of mutual engagement between medical professionals and patients, rather than a simple one-way transmission of information. The authors offer a profound current perspective on the nature of consent, with significant implications for clinical practice and medical research.

#### **4.2. Proposals for legislative changes**

Among the proposed solutions, we find a series of proposals for legislative changes aimed at obliging healthcare providers to fulfill three essential requirements regarding the consent form:

- Archiving: They must retain and keep a copy of the consent document in the patient's medical record;
- Transparency: It is necessary to provide the patient with the possibility to obtain a copy of the consent form they have signed;
- Obliging the healthcare provider to include in the informed consent form - and implicitly in the process of obtaining it - information regarding the patient's right to refuse certain aspects, such as the use of biological samples in future studies (which could be in contradiction with personal principles or beliefs) or the presence of students

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<sup>22</sup> Mihăilă, Camelia. "Informed Consent in Medical Law in the Romanian Legal System. A Comparative Law Perspective." 37-43.

<sup>23</sup> Mihăilă, Camelia. "Informed Consent in Medical Law in the Romanian Legal System. A Comparative Law Perspective." 37-43.

during consultations, without this negatively affecting access to treatment. The patient must be explicitly informed about this right, and this information should be clearly included in the informed consent document. Thus, it is ensured that the patient understands that they can selectively choose the aspects they agree with, without fear of being disadvantaged in terms of the medical care received. In our opinion, the best solution is to separate the three areas for which the patient must consent: for therapy, participation in research - including future research - and participation in clinical medical education, in the form of three different consent forms presented separately.

## **5. Conclusions**

The analysis conducted has led to highlighting a series of discrepancies between the practice in Romania regarding informed consent for medical procedures as an instrument for protecting autonomy, the right to life and dignity, and international practice in the field. More specifically, national practice is seen rather in a bureaucratic manner, as a form of compliance with a legal requirement that protects the doctor from malpractice accusations from the patient who has signed such an informed consent form, rather than as actual protection of patient rights.

A tendency was observed to approach informed consent as more of an administrative formality than a fundamental ethical process, in the sense of reducing the process of obtaining informed consent as an obligation for the doctor to counsel the patient to simply signing a form by which the patient accepts the doctor's good faith and competent action and exonerates them from malpractice liability. The informed consent form made available to the patient is often - in the analyzed forms - too general, allowing very few customizations arising in the doctor-patient relationship and having rather the form of an act of adhesion on the part of the patient to the treatment or intervention decided by the doctor, which the patient can generally accept or reject in its entirety.

A series of aspects that can be improved in the practice of obtaining informed consent, as well as in the legislation in the field, were noted. These aspects are manifested through:

- Partial overlap of different types of consent (for diagnosis, treatment, research, and medical education) in a single document, which can lead to confusion in the patient's mind regarding their right to refuse inclusion in research or participation in medical education without affecting their right to treatment. The lack of a clear delineation between consent for the medical act itself and that for the use of data or biological samples in future research is due, from our point of view to the inconsistency of legislation regarding patient rights on this issue and the relative ambiguity of the same legislation regarding the patient's right to refuse certain aspects without compromising access to essential treatment;

- The paternalistic approach observed does not, in our opinion, fully reflect the principle of patient autonomy and their right to self-determination.

In line with the consulted international practice - both medical and legal - and with the legislation regarding patient rights in countries such as Great Britain, France, and Germany, a series of improvements have been proposed regarding the regulatory framework for the use of informed consent to protect the patient's right to life and dignity. A series of suggestions for improving legislation have been proposed as follows:

- Clear separation of different types of consent;
- Explicit information to patients about their right to refuse certain aspects included in the informed consent form without consequences for basic treatment;
- Treating consent as an ongoing process, with periodic renewals for major procedures or significant changes in the treatment plan. Granting a time margin to the doctor, reimbursed by the Health Insurance House, for a more complete information and counseling of the patient about their health condition, in order to improve the process of obtaining informed consent.
- Implementation of a continuous consent process, with periodic renewals for long-term treatments or in case of significant changes in the treatment plan.
- Improving the doctor-patient communication process to ensure a real understanding by the patient of the information provided and implicitly of the implications of the decisions made.
- Adoption of a nuanced approach to informed consent, which takes into account the relational and social context of the medical act, in line with modern trends in bioethics.

We consider necessary a paradigm shift in the approach to informed consent, from understanding it as a simple administrative formality to recognizing informed consent as a fundamental ethical process that respects the autonomy, dignity, and rights of patients. The implementation of the proposed recommendations could significantly contribute to aligning Romanian practice with international standards, thus improving the quality of medical care and respect for patient rights in the Romanian healthcare system.

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