

# Legal Research & Analysis

## Informed Consent of the Patient

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**Abstract:** As a basic and general condition for the conclusion of the civil legal act, consent does not know a legal definition, this role being left to the doctrine. But the Romanian legislator dedicates a generous regulation to it in the Civil Code. Thus, consent was defined as a person's manifestation of will to conclude or perform a legal act. To produce legal effects, the consent must be conscious, free, and untainted. Consent, as provided by art. 1240 of the Romanian Civil Code, can be expressed verbally, in writing or through a behaviour that, according to the law, the parties, established between them, that leaves no doubt about the intention to produce the corresponding legal effects. Referring to the medical act and to the need for a valid and informed consent of the patient, we can define this informed consent, as representing the informed consent of the patient in relation to the interventions/medical acts that can have unpredictable consequences. However, to make an informed decision, the patient must be fully informed about his state of health, about the proposed medical procedures, about the potential risks and benefits of each procedure, about alternatives to the proposed procedures, about the diagnosis, the prognosis, and the progress of the treatment. As a rule, obtaining consent is done only after the patient is informed according to his capacity to understand, clearly and with direct reference to the medical act to be performed, communicating any useful information to make a fully informed decision of cause.

**Keywords:** Consent; Interdiction; Judicial Guardianship; Patient

### 1. Introduction

Every patient has the right to be informed about his state of health, proposed medical interventions, potential risks of each procedure, existing alternatives to the proposed procedures, including the failure to carry out the treatment, non-compliance with medical recommendations, and data about diagnosis and prognosis (article 6 of Law no. 46/2003). Similarly, article 22 of the Romanian Constitution guarantees the right to life and to physical and mental integrity. The Oviedo Convention provides in article 5 that an intervention in the field of health can only be carried out after the concerned person has given free and informed consent. In this context, the patient must receive adequate information in advance regarding the purpose and nature of the intervention, as well as regarding the consequences and risks. The European Charter of Patients' Rights of the European Union, in article 3 and 4 stipulates the right to information and informed consent of patients.

In certain situations, obtaining the patient's informed consent is not mandatory. In these cases, we are talking about exceptions to the informed consent rule. One of the exceptions refers to incapacitated patients (without discernment). These are people who do not have the capacity to understand the nature of their illness and are not able to appreciate the consequences of the decision to give or not consent. This situation occurs most frequently in case of mental illness or mental deficiency. For these people, the legal representative (guardian, curator) is authorized to give their consent for medical treatment if it is necessary. He acts with respect for the interests of the person under his care (he should make the same decisions that the patient would have made if he were able), the patient's previous decisions can guide in this direction. If the legal representative refuses and the doctor considers that it is in the patient's interest, the decision is declined to an arbitration committee made up of 3 doctors, for hospitalized patients, and 2 doctors for outpatients.

Lack of informed consent can attract malpractice liability. Depending on the circumstances, the responsibility of the medical staff can be civil (criminal), criminal, administrative or disciplinary. The current paper details these situations.

## **2. Clinical Studies and Person's Consent**

According to art.43 of Law no. 487/2002 on mental health and the protection of persons with mental disorders: "Clinical studies and experimental treatments, psychosurgery or others treatments likely to cause harm to the patient's integrity, with irreversible consequences, it does not apply to a person with mental disorders except with their informed consent of cause (s.n.), and subject to approval by the ethics committee within the unit of psychiatry, who must declare himself convinced that the patient really gave his consent, in knowledge of the case, and that it responds to the patient's interest". According to art.46 of the same normative act, "Conditions for assistance and health care mental health of persons serving prison terms or who are detained or arrested preventive and who have been determined to have a mental disorder, as well as the people hospitalized in the psychiatric hospital as a result of the application of the medical safety measures provided by the Code criminally, they cannot be discriminatory in relation to other mentally ill persons".

The provisions of art.701<sup>1</sup> paragraph (1) of Law no. 95/2006 on health reform, republished, with subsequent amendments and additions, regulates the fact that the "National Agency of Medicines and Medical Devices (NAMMD) authorizes and controls the studies clinics in the field of medicines for human use by checking compliance with good practices in the clinical study with or without therapeutic benefit, as well as the place of their implementation". According to paragraph (2) of the same article, "clinical studies are carried out in compliance with Principles and detailed guidelines on good practice in the clinical trial for drugs of human use for clinical investigation approved by order of the Minister of Health and the Norms with regarding the authorization of the venue, as well as those related to the implementation the rules of good practice in the conduct of clinical studies carried out with medicines for human use, approved by order of the Minister of Health, at the proposal of NAMMD".

According to art.4 point 4 of the regulation on organization and operation of the National Agency of Medicines and Medical Devices, approved by the Order of the Minister of Health no. 938/2016, this institution "authorizes and controls the clinical trials that are carried out, as well as the place of their implementation, for medicinal products for human use, in accordance with the guideline on good practice in the clinical study and with the legal provisions in the field in force".

It is pertinent to mention the norm of application of the Law on mental health and the protection of persons with mental disorders no. 487/2002, approved by Order of the Minister of Health no. 488/2016; Chapter VII entitled "Clinical studies carried out on adults with incapacity who are not in measure to express legal informed consent" within the norms regarding the implementation of good practice rules in the conduct of clinical trials with medicines for human use, approved by Order of the Minister of Health no. 904/2006. At the European level, regulation (EU) no. 536/2014 of the Parliament European and Council of April 16, 2014 on interventional clinical trials with medicinal products for human use and repealing Directive 2001/20/EC of the European Parliament and a Council of April 4, 2001 for approximation of legal acts and administrative acts of the member states regarding the application of good clinical practices in the case of conducting clinical trials for the evaluation of medicinal products for human use.

According to the Helsinki Declaration, chronic patients are vulnerable patients. Most of the patients are true social cases, being abandoned by their families and remaining hospitalized here for a long time, even until the end of life. So, in the case of clinical trials, patient consent is required for participation in the study.

Very clear criteria for the admission/selection of patients exists who are regulated, under rigorous procedures, and no clinical trial in Romania can be carried out without approval prior approval of the European Medicines Agency (EMA) or the American Food Agency Drug Administration (FDA).

Afterwards, the clinical trial, to start, goes through several stages, including the analysis of the National Ethics Council, the Ethics Commission of the hospital and the decision to the approval manager, depending on the assessment of the benefits of the study, the authorization being issued for carrying out clinical trials in the field of medicines establishes the points of work/department/location. Each study has subject information and consent document researched. It is mentioned that the subject can withdraw from the study at any time without sanctions. The form is drawn up in two copies: one for the investigator, one for the patient and is dated including the time of signing. In the observation sheet, it must be mentioned that the patient has been offered the opportunity to participate in the clinical study, that he was informed about the study medication, risks etc.

This procedure is mandatory according to EMA's Good Clinical Practice (GCP). A person's rights are practically unenforceable if there is not one special legal mechanism intended to offer special protection to the person in case of violation of its rights. In the sense of the mentioned, and vulnerable persons, in their capacity of consumers of health services, subjects of clinical tests, enjoy the special protection of the law, through the guarantees established for this purpose, represented by NAMMD. These guarantees are regulated by different normative acts, previously specified, which regulates the field of legal relations of medical law between the subject patient of the clinical trial and the medical framework monitoring the study.

We underline that, according to the civil law, the legal capacity of any subject, including a subject of medical law, it means both the ability to use, that is his general ability to have rights and obligations, as well as the capacity to exercise, that is the ability to exercise their rights and assume their obligations. In this sense, the capacity of the patient's legal status as a consumer of health services depends on several things criteria, the most important being the volitional criterion, which we suspect is often met only formally.

### **3. The Protection of the Person**

The protection of the person is one of the fundamental goals of the Romanian law system, each branch of law containing its own ways and methods to achieve this goal. The set of ways, protection methods specific to each branch of law constitutes "the system of legal means of human protection". The norms of civil law, through the regulations they contain, offer specific means of protection to the following categories of natural persons: minors, alienated and mentally retarded and those in special situations. These categories of vulnerable persons are also considered by the norms of other branches of law, such as family law, labor law and constitutional law (Dinu, 2020).

The regulation of special measures can be found in the Civil Romanian Code<sup>1</sup>, 3<sup>rd</sup> Title - "Protection of the natural person":

Art.104 Civil Code:

- (1) Any measure of protection of the natural person is established only in his interest.
- (2) When taking a protective measure, account must be taken of the natural person's ability to exercise his rights and fulfill his obligations regarding his person and assets.

Art. 105. Civil Code provides: "Minors are subject to special protection measures and those who, although capable, due to old age, illness or other reasons provided by law, cannot manage their assets or defend their interests under appropriate conditions."

Art. 106. Civil Code provides: (1) The protection of the minor is carried out by the parents, by establishing guardianship, by fostering or by other special protection measures specified by law.

(2) The protection of the major takes place by placing it under judicial interdiction or by the institution of receivership, under the conditions provided by this code.

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<sup>1</sup> The Romanian Civil Code. <https://splash-db.eu/policydocument/civil-code-law-2872009/> (Accessed 23 December 2023)

Each category of persons in special situations is regulated differently, having specific protection measures, such as: guardianship or conservatorship.

The protection of the minor is carried out by the parents, by establishing guardianship, by fostering or by other special protection measures specified by law. The protection of the minor takes place by establishing the measure of judicial counseling or special guardianship or curate or another measure provided by law. Guardianship is an institution for the protection of both the minor, who is deprived of the care of his parents, and the adult who is mentally retarded. The protection of the natural person through guardianship is carried out by the guardian. Guardianship is a measure ordering the temporary protection of a capable person, in certain situations that prevent him from exercising his rights, fulfilling his obligations, and defending his interests, such as advanced age, illness or physical infirmity.

#### **4. Special Guardianship as an Exception from The Obligation of Obtaining Consent**

A person can benefit from special guardianship if the deterioration of his mental faculties is total and permanent and it is necessary to be continuously represented in the exercise of his rights and freedoms. The establishment of special guardianship can only be done if adequate protection of the protected person cannot be ensured by the establishment of assistance for the conclusion of legal acts or judicial advice. Special guardianship can be instituted over a person whose complete mental faculties are totally lost and, therefore, cannot express valid and informed consent, in case of hospitalization or if submission to a medical act is necessary. The institution of special guardianship is ordered for a period that cannot exceed 5 years. However, if the damage to the protected person's mental faculties is permanent, the court may order the extension of the special guardianship measure for a longer period, which cannot exceed 15 years. Through the decision by which the protective measure was taken, the guardianship court appoints the person who will exercise the function of a guardian from the date the decision becomes final. In the absence of valid consent, the one who is able to give his consent for the sick person is the guardian appointed by the court.

#### **5. The Institution of Judicial Interdiction, Amended and Renamed After the Appearance of Decision 601/2020 of the Constitutional Court of Romania**

By Decision no. 601/2020, regarding the exception of unconstitutionality of the provisions of art.164 para. (1) from Law no. 287/2009 regarding the Civil Code, the Constitutional Court of Romania raised the alarm regarding the situation of those in need of protection due to mental suffering, to whom the measure of placing under judicial interdiction was applied, under the scope of art. 164 C.civ., measure found incompatible with provisions of the Romanian Constitution, as well as of the United Nations Convention on the Rights of Persons with Disabilities. The entry into force of Law no. 140/2022<sup>2</sup> brought into the highlights the rights of adults with intellectual and psychosocial disabilities,

By the Romanian Constitutional Court Decision no. 601 from 16.07.2021, the exception of unconstitutionality of art. 164 of the Civil Code, established that the provisions of this law are unconstitutional, the decision being published on 27.01.2021 in the Romanian Official Bulletin.

Art.164 Civil Code, as amended by Law 140/2022 provides: “the adult who cannot take care of his own interests due to a deterioration of his mental faculties, temporary or permanent, partial or total, determined following the medical and psychosocial evaluation and who needs support in forming or expressing his will, can benefit from counseling judicial or special guardianship, if taking this measure is necessary for the exercise of his civil capacity, under conditions of equality with other persons”.

A person can benefit from judicial counseling if the deterioration of his mental faculties is partial, and it is necessary to be counseled continuously in the exercise of his rights and freedoms. The institution of judicial counseling can only be done if adequate protection of the protected person cannot be ensured by the institution of assistance for the conclusion of legal documents.

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<sup>2</sup> Law no. 140/2022

A person can benefit from special guardianship if the deterioration of his mental faculties is total and, as the case may be, permanent and it is necessary to be continuously represented in the exercise of his rights and freedoms<sup>3</sup>. The establishment of special guardianship can only be done if adequate protection of the protected person cannot be ensured by the establishment of assistance for the conclusion of legal documents or judicial advice. Minors with limited exercise capacity can also benefit from special guardianship. However, when the court of guardianship assesses that the protection of the person can be achieved by the institution of guardianship or by placing him under judicial counseling, this measure can be ordered one year before the date of reaching the age of 18 and begins to produce effects from this date."

According to art.168 of the Romanian Civil Code<sup>4</sup>, as amended by Law 140/2022, it is stipulated that:

- 1) "The resolution of the request for the institution of a protective measure is made according to the provisions of the Code of Civil Procedure.
- 2) The institution of judicial counseling is ordered for a period that cannot exceed 3 years.
- 3) The institution of special guardianship is ordered for a period that cannot exceed 5 years. However, if the damage to the protected person's mental faculties is permanent, the court can order the extension of the special guardianship measure for a longer period, which cannot exceed 15 years.
- 4) Through the decision by which judicial counseling or special guardianship was instituted, the guardianship court establishes, depending on the degree of autonomy of the protected person and his specific needs, the categories of acts for which approval of his acts is necessary or, as the case may be, her representation. The court can order that the protective measure concerns only one category of documents. Also, the court can order that the protective measure refers only to the person of the protected person or only to his assets.
- 5) If the guardianship court proceeds according to paragraph 4, ordering the protective measure does not affect the capacity of the protected person. to conclude legal documents for which the court has established that the consent of the guardian or, as the case may be, his representation is not necessary.
- 6) The guardian or the representative of the protected person is obliged to notify the guardianship court whenever he finds that there are data and circumstances that justify the re-evaluation of the measure, as well as at least 6 months before the expiration of the period for which it was ordered, in order to re-evaluate them. The guardianship authority verifies the fulfillment of this duty, and in the absence of its fulfillment, it itself notifies the guardianship court. The court may order, following the same procedure, the extension, replacement or lifting of the measure".

The courts also take into account the following provisions: Art.50 and art.53 of the Romanian Constitution, Art.12 Para.4 of the UN Convention on the Rights of Persons with Disabilities.

The decision of May 31, 2016 pronounced in the case of A.N against Lithuania, under the aspect of art. 8 of the Convention for the Protection of Fundamental Rights and Freedoms, is also taken into account by the Romanian courts when pronouncing some solutions, taking into account that total incapacity implies major interference with the person's right to privacy and can only be done in exceptional circumstances, and the interference must be provided by law, pursue a legitimate objective and be necessary and proportionate.

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<sup>3</sup>Cimpoieru, N.C. "The patient's informed consent (Consimtamentul informat al pacientului)". <https://aliantapacientilor.ro/wp-content/uploads/2016/01/Articol-Consimtamentul-informat-CIMPOERU-CLAUDIA.pdf>.

<sup>4</sup> The Romanian Civil Code

Principles 3 and 6 of Recommendation No.R(99)4 of the Committee of Ministers of the Council of Europe establish that national legislation should, as far as possible, recognize that there may be different degrees of incapacity and that incapacity may vary over time, and "if a protective measure is necessary, it must be proportionate to the degree of capacity of the data subject and adapted to the individual circumstances and needs of the data subject".

## **6. The Procedure for The Institution of Special Guardianship Before the Court**

In judicial practice, as an exception to the rule according to which any medical act must be authorized or consented by the patient, the procedure of "the institution of special guardianship" is used by the interested persons (relatives of the patient). This institution appeared to replace the consent of the patient who, due to the disease and the reduced or non-existent degree of exercise capacity, cannot have a valid consent.

This procedure is quite difficult, the court being obliged to take all measures to avoid abuses that may arise as a result of the establishment of special guardianship. There were cases, where some people were banned and declared incapable, and the guardians were able to benefit from the monetary rights due to the patient (by raising the pension) or, they had certain pecuniary advantages, as a result of trading the assets of the ill person. The procedure for resolving claims brought before the court can be found in Title II, art. 936-943 from the Romanian Civil Procedure Code. Therefore, the procedure for the establishment of special guardianship requires that a person, usually a relative of the patient, addresses to the Court, with a claim, requesting the court to order the establishment of special guardianship for a period of 5 years and its appointment as tutor. The one who formulates the request has the status of petitioner, and the patient has the status of respondent.

The request before the court is formulated when there has already been a diagnosis of the patient, a certificate of disability, or a psychiatric evaluation performed by a specialist doctor. Once invested with the request, the court requests the Prosecutor's Office, based on art.938 from the Romanian of Civil Procedure Code, to carry out preliminary investigations regarding the respondent. The prosecutor invested in the case, issues an Ordinance ordering the performance of a medico-legal psychiatric evaluation. A social investigation is also ordered. After carrying out these works, the prosecutor issues a new Ordinance by which he orders the submission of the works and the report to the court, also expressing his opinion, in the sense of admitting or rejecting the summons request. The court orders the appointment of a curator, usually a lawyer, who is obliged to represent the interests of the patient.

Although the provisions of art. 940, 2<sup>nd</sup> paragraph of the Romanian Civil Code provide for the obligation to listen directly to the sick person, either in the courtroom or at the place where he is found, there are situations in which it is appreciated that this listening is no longer required, due to the conclusions of the documents existing medical records on file. In practice, one can observe the weight with which the sick is brought to the courtroom, one observes the state of embarrassment of the family members, one observes even the state of discomfort in which the judge is placed, the sick being with psychiatric conditions and having a different behavior. According to the provisions of art.941 Romanian of Civil Procedure Code: "After the judgment of injunction has become final, the court that pronounced it will immediately communicate its decision in a legalized copy, as follows:

- a) To the local community public service for the record of the persons where the birth of the one placed under judicial interdiction is registered, in order to make a mention on the side of the birth certificate;
- b) The competent health service, in order for it to establish a permanent supervision over the person placed under judicial prohibition, according to the law;
- c) The competent cadastre and real estate advertising office, for recording in the land register, when appropriate;
- d) The trade register, if the person placed under judicial prohibition is a professional."

This communication of the decision, to all these institutions, has the role of verifying the fulfillment of the guardian's duties.

## 7. Case Study

By civil sentence no. 9583/2023 of the Brasov Court of Law<sup>5</sup>, Romania, the petitioner B.I, the respondent's son, requested the court to establish special guardianship, for a period of 5 years, of the respondent T.S and to appoint him as guardian. In the motivation of the summons request, it is shown that the respondent no longer has the necessary discernment to take care of her interests.

In law, the provisions of art.164-170 of the Romanian Civil Code were invoked, and in probation, written evidence was requested. Pursuant to the provisions of art.938 paragraph 2 of the Civil Code, the court appointed an *ex officio* lawyer to defend the interests of the respondent. During the judicial investigation, the court administered the written evidence. From the medical and psychological evaluation report drawn up in the case, it appears that the respondent presents the diagnosis of moderate-stage mixed dementia with psychotic elements. It was also noted that the respondent does not have the ability to make informed decisions, has a low degree of autonomy, and does not have the ability to take care of herself or her property. He needs permanent assistance in his daily life, either from the family or through a specialized institution. The prognosis is reserved, being a deteriorating condition. The evolution will most likely be negative, with the degradation of all mental functions, taking into account the associated pathology, age, and existing symptoms up to now. He needs psychiatric and somatic dispensation, with the need for legal, social and psychological assistance.

The conclusions of the medical evaluation report are also reinforced by the conclusions of the psychological evaluation report, from which it follows that the respondent requires permanent protection, care and supervision. The court also considers that the petitioner is the son of the respondent, being the person who supports him and who takes care of the respondents' property. In law, the court considers applicable the provisions of art. 164 of the Romanian Civil Code, as amended, art.168 of the Civil Code, art.50 and 53 of the Romanian Constitution and art.12 paragraph 4 of the United Nations Convention. In view of the legal provisions shown, the court appreciates that the respondent does not have discernment or the ability to understand the consequences of her actions, lacking the mental possibility of self-control. It is found that the state of mental health is clearly altered, as it appears from the medical documents submitted to the case file.

The court shows that the measure of special guardianship pursues a legitimate objective, as it represents a measure to protect the patient, being at the same time necessary, in a democratic society, so that a guardian has the opportunity and the obligation to ensure the well-being of the patient and offer him proper care. The court assesses that special guardianship is required for a period of 5 years, and at the end of this period, the mental state and mental competence of the respondent must be reassessed in relation to the legal provisions in force from the time the request was made. The court will prioritize a relative, a relative or a friend of the respondent as guardian, taking into account the personal relationships, the material conditions and the moral guarantees presented by the person called to guardianship, according to the provisions of art.114-120 Romanian Civil Code. In this case, the petitioner is the respondent's son; he is the one who took care of the respondent's well-being, providing her with permanent moral and financial support. Therefore, seeing that the petitioner presents moral and material guarantees, as well as the fact that he expressed his availability to be appointed guardian, the court assesses that the conditions stipulated by the law are met.

The guardianship will be exercised only in the interest of the respondent, both in terms of the person and his assets, the guardian representing the respondent in relations with third parties, as well as in front of institutions and public authorities when concluding civil legal acts of preservation, administration and disposition of the Guardian it will be forbidden to carry out any act of disposition on

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<sup>5</sup> Civil Decision no.9583/23.10.2023, Brasov Court of Law, <https://portal.just.ro/SitePages/acasa.aspx>

behalf of the respondent, without the prior authorization of the guardianship court. In accordance with the provision of art.174 of the Civil Code, the place of care of the protected person will remain at the residential center where he is hospitalized. In view of the documents and works of the file, the court admits the summons request and orders the institution of special guardianship.

## **8. Conclusions**

We can appreciate that the patient's informed consent is an intrinsic component of the medical act, which cannot be separated from it. So it can be said that the medical act involves at least two essential components: an ethical component (which includes informing the patient and obtaining his consent) and a scientific one (which includes the actual prevention, diagnosis and treatment procedures). As we have shown in this paper, beyond the obligation to inform the patient in order to obtain consent, there are also exceptions to the rule, clearly regulated exceptions, which facilitate this process of obtaining consent, by appointing persons who can represent and express consent valid in place of the person lacking capacity. Although the procedure used to appoint the guardian/curator is a difficult one, which involves the competition of several institutions and several people, we appreciate that, in order to avoid any abuses and to guarantee the patient respect for his fundamental rights, this detailed verification is more than necessary.

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