Note

The text is an unofficial reproduction of the normative act and is informative. For the official version, please consult the Official Gazette of the Romanian Government.

Decision no. 15/2016

On the elements of the patient's informed consent

Published in the Official Gazette of the Romanian Government, Part I no. 1040 of 23.12.2016

Pursuant to art. 534 of Law no. 95/2006 on health care reform, republished, with subsequent amendments and completions, taking into account the provisions of art. 660 of the same normative act,

The National Council of the Romanian College of Dentists adopts the following decision:

Art. 1. - In order to subject the patient to methods of prevention, diagnosis and treatment, with potential risk for him, the dentist will request the written consent, in accordance with the law.

Art. 2. - The written consent of the patient, necessary according to art. 660 of Law no. 95/2006 on health care reform, republished, as subsequently amended and supplemented, must contain at least the following elements:

a) the name, surname and domicile or, as the case may be, the patient's residence;

b) the medical act to which he/she is to be subjected;

c) a brief description of the information provided to him by the dentist;

d) the unequivocal agreement for performing the medical act;

e) signature and date of expression of the agreement.

Art. 3. - The elements of the informed patient's agreement are provided in the model recommended in the annex which is an integral part of this decision.

Art. 4. - The written agreement constitutes an annex to the primary evidence documentation.

Art. 5. - On the date of entry into force of this decision, the Decision of the National Council of the Romanian College of Dentists no. 2/2013, not published in the Official Gazette of the Romanian Government, Part I.

Art. 6. - This decision is published in the Official Gazette of the Romanian Government, Part I.

The President of the Romanian College of Dentists,

Ecaterina IONESCU

București, 19th Nov 2016.
No. 15.

Annex

Patient's informed consent

1. Patient information			
1.1. Full name			
1.2. Domicile/residence			
2. The patient's legal representative * * Used in the case of minors or adults without discernment.			
2.1. Full name			
2.2. Domicile/residence			
2.3. Relation with the patient			
3. The medical act (description)			
4. The following information has been provided to the patient in connection with the medical act:			
		Yes	No
4.1. Information on health status			
4.2. Diagnosis			
4.3. Prognosis			
4.4. The nature and purpose of the proposed medical act			
4.5. Proposed interventions and therapeutic strategy			
4.6. The benefits and consequences of the medical act, insisting on the following:			
4.7. The potential risks of the medical act, insisting on the following:			
4.8. Viable treatment alternatives and their risks, emphasizing the following:			
4.9. Risks of not performing the treatment			
4.10. Risks of non-compliance with medical recommendations			
5. Consent to collect			
		Yes	No
5.1. The patient agrees to the collection, storage and use of organic products			

6. Other information that has been provided to the patient		
	Yes	No
6.1. Information about available medical services		
6.2. Information on the identity and professional status of the staff who will treat him/her * * Identified in the table with the medical staff who provide health care to the patient		
6.3. Information about the rules / practices in the medical unit, which they must follow		
6.4. The patient was informed that he/she was entitled to a second medical opinion		
7. The patient wishes to be further informed about his state of health	Yes	No

I) I ACCEPT THE PERFORMANCE OF THE MEDICAL ACT		
I) I, the undersigned ____ * declare that I have understood all the information provided by ____ **, listed above, that I have presented to the dentist only true information and that I express my informed consent to perform the medical act. * Name and surname of the patient / legal representative. ** Name and surname of the dentist who informed the patient.		
.... (Signature of the patient / legal representative who consents informed when performing the medical act)	Date:	Time:

II) I REFUSE TO PERFORM THE MEDICAL ACT		
I) I, the undersigned ____ * declare that I have understood all the information provided by ____ **, listed above, that the consequences of the refusal of the medical act have been explained to me and that I express my refusal to perform the medical act. * Name and surname of the patient / legal representative. ** Name and surname of the dentist who informed the patient.		
.... (Signature of the patient / legal representative who consents informed when performing the medical act)	Date:	Time:

Table with medical staff

who provides healthcare services to Ms/Mrs./Mr. ....

No	Family name, name	Profession	Professional rank/specialty
1			
2			
3			
4			
5			
...			