INFORMED CONSENT

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(Summary)

In the present society, the development of medicine, biology and technology leads to new diagnostic and therapeutic opportunities. This makes today's patient expectations are much higher than in the past. The informed consent is the patient accept to be subjected to methods of prevention, diagnosis and treatment only after their explanation by the physician (Law 95/2006 on healthcare reform). The concept of "informed consent" was developed starting from two distinct components: the right of a person to decide what will happen to his body, and the doctor's duty to provide sufficient information so as to ensure that the final decision of the patient is based on significant knowledge of its status and as the options of the treatment and all risks are known and perceived in real prognosis order.

In relationship of medical law, the rule is that the obligation is an obligation of medical means, doctor is required to make all diligence efforts to cure patients, and in case of one negative outcome in the process of healing the patient, is not automatically equivalent with the failure practice.

In the wrongful act that caused patient harm could have been avoided in the doctor practice with the diligence required by law, he will be liable to disciplinary, civil or criminal liability thereof, depending on the circumstances of the offense and the severity of an injury.

Keywords: *informed consent, medical law, medical practice ,legal liability*

The civil legal relationship is represented by the social relation, patrimonial or non-patrimonial, governed by the rules of civil law.[1] The legal relationship of medical law is a social relation that seeks the satisfaction of material or different other interests regulated by legal rules , where the parties (doctors, patients, companies) appear as holders of the rights and, accordingly, the mu-

1 Boroi Gabriel, *Drept Civil.Partea generală.Persoanele*, Bucuresti,Ed Hamangiu, 2008, pag 4

tual obligations, supported if necessary, by the coercive force of the state.[2]

It is a :

-social relationship, between people (physician-patient);

-mutually-willful relationship, because the social relationship becomes a civil legal relationship through the will of the legislator, materialized in the legal texts which regulate it, and also through the expressed will of both parties (the patient has the right to choose their own physician);

-the two parties have equal legal position (insubordination of the doctor toward the patient or of the patient toward the doctor);

In the medical practice, the physician-patient relationship acquires contractual content. Therefore, the medical legal act involves the manifestation of the will, clearly intended to take legal effect, meaning to create, modify or extinguish a legal medical relationship.

Essential (general) conditions necessary for the validity of this relationship are:

-ability (capacity)

-valid consent of the party that undertakes the obligation

-a determined object

-lawful cause

The consent represent the essential condition of the substance, and general medical legal act, which stays in the decision to achieve such an act. To be valid, consent must meet the following conditions:

- come from a person with discernment;
- be expressed intention to produce legal effects;
- to be explained;
- not to be altered by any vice of consent (error, fraud /tricked, violence).[3]

The informed consent is the patient accept to be subjected to methods of prevention, diagnosis and treatment only after their explanation by the physician (Law 95/2006 on healthcare reform, Title XV civil liability of

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2 A.T. Moldovan, , *Tratat de drept medical,* Bucuresti,EdAll Beck, 2002 , pas 149

3 Beleiu George, *Introducere in dreptul civil*,Bucuresti, Ed Sansa, , 2000 , pag 152

medical personnel, Chapter 3, article 8). The concept of "informed consent" was developed starting from two distinct components: the right of a person to decide what will happen to his body, and the doctor's duty to provide sufficient information so as to ensure that the final decision of the patient is based on significant knowledge of its status and as the options of the treatment and all risks are known and perceived in real prognosis order.

The doctrine of the informed consent in the context of doctor-patient relationship reveals that one of the first documented cases, unauthorized treatment by the patient, in 1767, when two british surgeons have removed a vicious callus to align of the bones after a fracture of the femoral bone. In the process that followed, Slater vs. Baker and Stapleton, the court decided that, ,,is the practice and the law of the surgeons to obtain consent from the patients before surgery , and the two surgeons violated the well known and accepted rule of the consent".[4]

In the United States, in 1914, when New York Hospital versus Schloendorff, have had complains of unauthorized surgery during a authorized diagnostic exploration. Ms. Schloendorff addresses to New York hospital for major abdominal pain. The doctor has ask the patient to consent an exploratory laparotomy, during which highlights the existence of an abdominal tumor, which a doctor removes without the prior consent of patients for this therapeutic process. In this case, the judge decides that ,, each human being has the right to determine what is done with your body, and a surgeon who performs an operation, with out the patient consent commits an assault for which he is responsible ".[5]

The twentieth century connects existing consent to the ethical medical trials using human subjects in research, practice that lead to unimaginable abuses. The test of the scorbutus treatment by James Lind in 1747 the British sailors was done without the existence of an consent in prealabil.[6]

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4 După Simon R, *Clinical Trials*, Lippincot& Wilkins, 2002, quoted by Bild Eduard ERR vol 2, no April 2004

5 Mabel Marijuana, Dolores Ruiz, Universidad del País Vasco (UPV-EHU). Dpto. Medical *Especialidades Quirúrgicas. Y Forense Area Legal Medicine, Curso: Bioethics*. OCW. ENERO 2009

6 Graham Sutton, 'Putrid *Gums and' Dead Men's Cloaths* ': James Lind aboard the Salisbury,' Journal

German state, has endorsed the brutal medical experiments that took place ever. Prisoners in concentration camps were subjected to barbaric research. At Nurnberg (The war crimes tribunal), the defendants were arguing that the voluntary accord was not necessary. This defense was rejected by the judges of the tribunal, and in 1947 Nurngerg Code was drawn up covering the fundamental principles governing research on human beings and which condemn scientific research carried out in inhuman conditions regardless of the results. According to this, human subjects that participate in research should have legal capacity to express their consent ,and they should exercise their right to choose free of will, without intervention of any element of force, fraud, deceit. Also, subject in matter should have sufficient knowledge and understanding to enable him to take a proper decision.

The term "informed consent" was first used in 1957 (Leland Stanford University Salgo versus the Board of Directors) , and is a milestone stating that doctors have a legal obligation to present positive information about the risks, benefits, and alternatives evaluated patients / treated. Claimant, aged 55, complained of pain in hips and lower back. He also had abdominal pain on the right side. He was diagnosed with a probable occlusion of the aorta abdominal. They recommended thorough assessment of his condition. One of the examinations that the doctor wanted to do, was to evaluate the aorta, the maneuver that is done under anesthesia, by injecting a contrast agent into the aorta and x-ray examination to locate the blockage. The next morning when he awoke, the claimant found out to be paralyzed. His condition was irreversible one.[7]

Evidenced by informed consent information can be appreciated that "reasonable for the physician" (Natanson vs. Kline, 1960 - so how much information a physician deems it necessary to be provided to the patient), or as "reasonable for the patient" (Caterbury V. Spence 0.1960 - so how much information the patient needs).Practice shows that the courts appreciate the model " reasonable for the patient ".

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of the Royal Society of Medicine (2003)

7 Salgo v. Leland Stanford, etc. Bd. Trustees, 154 Cal.App.2d 560

The period 1960-1970 is one in which human beings are condemned experiments. "Business thalidomide" is known as one of the biggest medical tragedies of modern times. Thalidomide is a drug used for its anti-inflammatory and immunosuppressive properties. It was sold in several countries around the world from 1957 until 1961 as hypnotics (insomnia). Many pregnant women prescribed thalidomide caused babies phocomelias (malformations of the limbs, hands and feet are directly related to the trunk). Tuskegee experiment (known as the Tuskegee Syphilis Study) was a negative clinical trial conducted between 1932 and 1972 in Tuskegee, Alabama by the U.S. Public Health Service to study the natural progression of syphilis in men from rural areas who believed to have received free medical assistance from the american government. This study in 1979 led to the development of the Belmont Report. This statement includes fundamental ethical principles that should underpin research on human subjects: the principle of autonomy, the nonmaleficience , of beneficence and justice.[8]

Declaration of Helsinki, developed by the World Medical Association in 1964 in "The 18th World Medical Assembly" and re-evaluated in 1975 in Tokyo, "The 29th WMA", and in Madrid in 2000, defines the ethical conditions of the experiment in humans, based on the values contained in the Declaration of Rights, points out that the first obligation of the doctor is to give medical or health advice to the patient. Any advice or medical act addressed to a patient in somatic or mental suffering should be performed only in spirit of usefulness for pacient.[9] It follows that a properly informed consent on diagnostic methods, treatment and inclusion or continuation of clinical trials involving human subjects is essential to avoid situations such litigation, medical tragedies, especially for obtaining maximum satisfaction results for both physician and patient.

The patient, like any human being is principal subject of low. The soul and the body can not be separate. That means ,you can not make contracts on its own body, parts or functions. Rules established by experts are based

8 Tuskegee Study - Timeline . NCHHSTP. CDC. 25/06/2008. Retrieved 04/12/2008

9 Enache Alexandra, *Etica și legislația privind practica medicală*, www.umft.ro/newpage/structura/ET_doct_06.pdf

on both efficacy and safety of medical act , and also avoiding conflicts in situations that may occur between physician and patient. If in the past there was a subordination of the patient to the doctor, now they are in conditions to maintain an equal balance in between them. For this partnership, the patient is free to choose the doctor who treated him and participate in decision making. Patients' rights were the subject of the meeting in March 1994 in Amsterdam (Netherlands), organized by the World Health Organization, attended by delegates from 36 states. Adopted document was " The declaration on the rights of patients in Europe". Romania adopt on January 21, 2003 Law No. 46/2003 witch regulates patient's rights. At Chapter 3, is regulated informed consent for medical intervention.The legislator understands by the medical intervention "any examination, treatment or other medical act preventive diagnostic purposes , treatment or rehabilitation"(Article 1, letter d of law mentioned).

Consent is based on the principle of autonomy (self-determination), that each individual is responsible both for their own actions and for the body. The doctor can not act as a judge of the patient's values, but will respect individual autonomy. This way, human rights are individual and defensive (in front of legislative excesses), affirmative and positive (under witch social interests follows). The human rights stays at the bottom of patients' rights.[10]

General consecration of the principle of consent is found in chapter II of the Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997. The *general rules of this principle is expressed in article 5:*

- an intervention in health can be made only after the person has given consent freely and knowingly

- to the patient must first be provided with appropriate information concerning the purpose and the nature medical intervention, and the consequences and risks attached

-the patient can withdraw at any given time his consent

10 Gh. Scripcaru , *Bioetica între ştiinţele vieţii şi drepturile omului*, Romanian Journal of Bioethics, Vol. 1, no. 2. 2007

THE STEPS TO ENSURE INFORMED CONSENT

The first stage:

Disclosing the truth about the condition of the patient - is the provision of relevant information by the physician, information on diagnosis and treatment, and their understanding by the patient.

So, any decision regarding treatment belongs to the patient, the doctor being the adviser. To be legal, the patient consent should be informed. The patient rights to information is also stipulated in Law No. 46/2003 regarding patient rights:

-right to be informed of the medical services available and how to use them (art 4)

-right to be informed of the identity and professional status of health service providers (article 5 , paragraph 1)

-right to be informed of the rules and practice that must be met during hospitalization period (article 5, paragraph 2)

-right to be informed of his condition, the proposed medical interventions, the potential risks of each procedure, the alternatives to the proposed procedures, including failure to medical treatment and failure to comply with recommendations and data on diagnostic and prognostic (article 6)

Consent is valid only if given with direct reference to the recommended medical act. The patient must be able to understand the significance of information, to draw relevant conclusions and the decision to be a rational choice between accepting. For the right choice of accepting or refusing the treatment, " the information to the patient shall be made known in a respectful language, clear, with as less specific terminology as possible. If the patient does not speak Romanian, information should be made known in their native language or the language they know or, if necessary, will find another form of communication "(article 8, Law 46/2003). This aspect can be found in art 8 of Law 95/2006 on healthcare reform, Title XV, a civil liability of medical personnel.[11]

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11 Art.8 of *medical malpractice law:* Patient's informed consent is to be subjected to methods of prevention, diagnosis and treatment after their explanation by the physician according to par. (2) and (3).In obtaining informed consent, the doctor is obliged to disclose patient information to a

Information provided by the physician, about the proposed treatment should include the following:

-description of the treatment (nature, the conduct, purpose, prognosis)
-adverse effects (including discomfort and pain)
-possible complications and risks
-new optional treatments ,without proven efficacy in the test of time
-perspectives of an alternative treatment
-consequences of no treatment

It is necessary to maintain a balance in providing the information. Is know that their abundance reduces patient's ability to make choices without oscillate in one direction or another. Your conduct should avoid wake of the image of a more serious disease than it is in reality (article 27, Chapter II, Code of Deontology of the Medical College in Romania).

The patient has the right to expressly ask not to be informed and to choose another person to be informed in his place, and also has the right to decide if longer wishes to be informed when the information presented the physician would cause suffering (article 9 and article 7, Law 46/2003).

There are exceptions to the law on health information in accordance with article 33 paragraph 5 of Law 487/2002, mental health law and the protection of persons with mental disorders:

a) the disclosure of medical documents may also be detrimental to physical and mental health, this being determined by the chief physician or the physician;

b) have been a written specification of the risk of this effect on the patient's file, applied only to persons who are patients in the present, nor former patients.

Stage two:

Capacity of decision by the patient - is to check their way of understanding of presented data, to establish if the patient understands/agrees with what's going to happen according to the suggested medical intervention.

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reasonable scientific understanding of patient capacity. The information should include: diagnosis, nature and purpose of treatment, risks and consequences of proposed treatment, treatment alternatives viable, risks and their consequences, prognosis without treatment.

-the patient's consent is a imperative for any medical intervention (Chapter 3 of The declaration of promoting patients' rights in Europe, Amsterdam 1994).

-consent will be given after informing the patient about the diagnosis, prognosis, therapeutic alternatives, their risks and benefits (article 60 of The Code of Deontology of the Medical College in Romania).

-patient has the right to refuse or stop medical intervention assuming, in writing, responsibility for its decision, the consequences of refusal or stop medical documents must be explained to the patient (article 13 of Law no. 46/2003, patient rights law)

- patient consent is required for the collection, preservation, use of all biological products taken from the body, in order to establish the diagnosis or treatment with which it agrees (article 18 of Law no. 46/2003, patient rights law)

-clinical trials and experimental treatments, psychosurgery or other treatments likely to cause bodily integrity of the patient with irreversible consequences, does not apply to a person with mental disorders than with its consent, knowingly, and subject to approval by the Ethics Committee of the psychiatric unit, which must be convinced that the patient really has given consent, knowingly, and that serves the interest of the patient (article 37 of Law 487/2002, mental health and protection of persons with mental disorders)

-patient-consent is mandatory for its participation in clinical medical education and scientific research. Can not be used for scientific research that people are unable to express their will, except to obtain consent from the legal representative and if the research is done and the patient's interest (article 19 of Law no. 46/2003, patient rights law)

-patient can not be photographed or filmed in a medical unit without his consent, unless the images are needed and avoid diagnosis or treatment of a suspected malpractice (article 20 of Law no. 46/2003, patient rights law)

Stage three:

Voluntary adherence (independent decision) - is expressed by the patient's right to decide freely without constraints or manipulation of any type of medical intervention that directly affects him.

The legal age to express informed consent is 18 years, according to article 650 of law 95/2006 on healthcare reform, and in art 9 of Law 95/2006 on healthcare reform, Title XV, a civil liability of medical personnel. According to the same two pieces of legislation, there are two exceptions to the legal age in the following situations:

a) emergency situations, when parents or guardian can not be contacted, and the minor is necessary discernment to understand the medical situation that is in;

b) medical situations related to diagnosis and / or treatment of sexual and reproductive issues, the request of the child over the age of 16;

EXCEPTIONS TO THE RULES INFORMED CONSENT

Common situations encountered in practice are:

-when the patient can express their will, but is required emergency medical intervention, medical staff have the right to deduct from a patient's previous expression of the will it (article 14, Law no. 46/2003, patient rights law)

-if the patient requires emergency medical intervention, the legal representative's consent is not necessary (article 15, Law no. 46/2003, patient rights law)

-when the intervention is in the interest of the patient and their legal representative refuses to give consent, the decision is invested to specialty comity of arbitration panel to decide (article 17, Law no. 46/2003, patient rights law).

- in case of minor patients, incompetent or can not express their will, legal guardians are entitle to give the consent .If your doctor finds that the decision is not the legal representative of the patient's interest, it is a special arbitration panel to review the case and make a decision (article 61 of The Code of Deontology of the Medical College in Romania)

- in emergency situations when the patient's life is in danger and he is expressing the will and relatives or legal representatives can not be contacted, consent is implied, and the doctor will do everything possible to save the pa-

tient, following the its information to be made later (article 62 of The Code of Deontology of the Medical College in Romania)

-in all other cases the patient is unable to give consent and where there is no legal guardian or one appointed by the patient for this purpose, appropriate decisions must be taken to substitute decision-making process, taking into account what is known and, if possible, that it can be assumed about the patient's wishes. (Chapter 3 of The declaration of promoting patients' rights in Europe, Amsterdam 1994)

-psychiatrist may establish treatment without obtaining patient consent in the following situations (article 29 of Law 487/2002, mental health law and the protection of persons with mental disorders):

a) the patient's behavior is an imminent danger of harm to himself or other people;

b) the patient has no mental capacity to understand the condition and need for medical treatment;

-treatment of irresponsible patients with transmitted diseases

-giving the patient the right not to be informed about his illness

-the need to expand an operation when the patient is still under anesthesia (this situation is advice to be mentioned in the first consent agreement).

AGREEMENT ON INFORMED CONSENT

Besides the legal representative consent, the patient can express himself agreement or disagreement, even if this event does not have the power of the consent:

- patients (whether minor or adult) must still be involved in decision-making process, as long as the capacity of understanding (Chapter 3 Declaration on the Rights of patients in Europe, Amsterdam, 1994).

-must be respected and the incapable patient's point of view, to the extent that there is no risk of injury to themselves or someone else, knowing that not every type of law disturbed or unbalanced thinking cancels mental capacity of the individual.

-a child who is able to form their own views has the right to express them freely, and these views must be taken into account, their share in the decision is consistent with the age and maturity of the child.

HOW TO OBTAIN INFORMED CONSENT

In the medical fields is an increase of patients desire to information about the medical act. However, informed consent is seen as a bureaucracy step and not a stage of care. Moreover, it is becoming more important as legal document witch supports medical attitudes in case of lawsuit.

Attention to obtaining consent means:

-doctor-patient discussions to take place in health care facilities in which will take place the medical act, if possible in the doctor's office

-information to be made gradually from simple to complex, depending on the patient's desire to be informed and the degree of understanding

-the information presented not to use excessive terms, to be clear, concise, without willful omissions

-will highlight on the benefits, risks, side effects and complications of care proposed

-will present all the alternatives

-doctor will answers questions from patient and give them enough time to decide on their own

- to the patient is given the informed consent form completed, which he reads, and if there are any issues that are unclear to the patient , they will be explained by the doctor

- signing the form

In practice we can see that it is difficult to provide sufficient information on the diagnosis and the therapeutically options. There are situations in which patients trust doctors chosen, and their consent can be granted without understanding consequences. Other times patients do not understand the information presented and have unrealistic expectations from the medical act suggested. Some patients do not trust Romanian medical system and believe that available treatments are not the best and they are seeking " guarantees", which makes the doctor to try to "cover himself" thru the same contract, as moving away together from the principle of consent (rational choice between acceptance and refusal of treatment proposed by the balancing of benefits and disadvantages).

Negative version of informed consent is the informed refusal from the patient.

INFORMED CONSENT FORM

Consent form must contain:

- the identification information of the person who signed it
- the status (patient, legal representative, family members)
- mention of explaining, in accordance with the patient understanding meaning, purpose, benefits and risks of medical procedure
- writing down the treatment / surgery / investigation
- appointing of a doctor (noting the name of)
- mention the risk acceptance, free acceptance of medical intervention for the personal benefit
- a note that did not receive any guarantee or assurance for the outcome
- acceptance of the proposed type of anesthesia
- nominal identification of the anesthetist
- the authorization of the medical team that in unforeseen situations that may arise in the course of the medical intervention to act in the interest and benefit to patients at their best abilities , professional skills and experience
- the statement under which consent is given freely and knowingly
- an explanation that no improper benefits was claimed by medical team
- certification of the patient that he has read, understood and accepted as full data content of consent forms
- patient signature
- signature of the doctor who performed information and obtaining informed consent
- date

TIPE OF THE INFORMED CONSENT

Giving consent can be done in two ways:

1. Default:

In current medical practice such consent is at the doctor-patient relation. When the patient is currently engaged in doctor's office consultation he agrees to an investigation or future treatment .This is a consent tacitly assumed (eg: consent to the collection of blood by simply opening the sleeve of his shirt and giving hand to perform the procedure).

2. Explained:

In this version, the patients will give permission and accept the medical benefits and risks.

This can be obtained in several ways:

- in writing (in accordance with article 13 of Law no. 46/2003, patient rights law)
- verbal (in the presence of another doctor or medical staff)
- based on confirmed authentic video recording
- with verified witnesses from outside the medical unit

INFORMED CONSENT AND MEDICAL PRACTICES

The informed consent in medicine has an imperative value. It has a specific connotation depending on the medical fields. I will present you some examples of informed consent used in pediatrics, in genetics, in the organ donation and transplantation and in the scientific research and clinical studies.

In pediatrics

The concept of informed consent in pediatric practice was described for the first time in 1976, by the American Academy of Pediatrics.[12] The lately development of science, medicine and ethics require new concepts about the children's rights and the pediatric patients in the modern society. The child is not a "property" of their parents or "miniature adult". The pediatricians who take care of the pediatric patients must respect in their medical practice the same ethical, moral and legal rights as for an adult patient.

Specific to this period is how is obtain the informed consent, because of the limited ability of the patient to understand his clinical situation. The pediatric patient is a vulnerable subject because of his age, so he cannot provide informed consent. This fact is presented in Chapter 3, Declaration of promoting patients' rights in Europe, Amsterdam, ,1994. In Romania this aspect was enacted in the year 2003 (Law 46/2003- Patient rights law). According to

12 American Academy of Pediatrics Task Force on Pediatric Research, *Informed consent and Medical Ethics*, Pediatrics, vol 57, 1976

this law, any medical act must be performing with the informed consent of the patient or his legal representative.[13] According to the Law no. 272 from the year 2004 about the protection and promotion of child rights, the parents must request the proper medical care for their child (article 43). They are the most interested in their children's sake. Therefore they are considered to be the only persons who are able to take the best decisions for their children from the first moment of their life.

Every child (newborn, infant, toddler, or teenager) should be treated like other patient, taking into account his own interests. Also his parents must be involved in taking decision and in their absent, the legal representative must guaranteed for the child rights.

The neonatal period:

In this stage, the parent-child relationship is special: the newborn doesn't speak, while the new parents don't know very well their child. The family can be overcome with proper medical care and sometimes, the life style of the family explains why the newborn child's interests are not the same with those of his parents. The born of a baby with medical problems (respiratory distress syndrome, cardiac malformations or perinatal asphyxia severe, etc.) can affect the delicate balance of the affected family. Many times they refuse to believe that the bad news is real.

Tension and conflict may occur between parents and neonatologist when physicians believe that the treatment is useless or even dangerous for newborns, especially the premature one and their family. The doctor should not prescribe or continue a treatment that they consider it is harmful or unethical. But what represent a useless treatment? Sometimes a parent can believe that a procedure can be regarded as necessarily for his child although this may be considered as unnecessary for the physician. The ventilation of a newborn without any chance to survive or minimal social interaction may be sufficient for parents. This thing can explain the depression of the family. This medical problem represents a destabilizing factor for the family, with emotional and material implications.

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13 Bogdan C, *Observații privind respectarea dreptului la consimțământ informat la subiecții competenți și la cei vulnerabili,* Romanian Journal of Bioethics , vol. 1

The parents must be informed about the medical situation of the newborn, his health or outcome in order to take a correct decision. It depends on the persons who gives the information or the way it is done. The neonatologists must present clear information about the patient, his disease, the treatment options, and the prognosis.[14]

The informed consent of the parent based on his right to choose can be difficult due to the divergent views. There are situations where, following discussions with parents, they require further effort to keep in life their newborn, regardless of consequences. After a period of admitted in intensive care units, a prolonged hospitalization, a maternal education necessary care and a desperate attempts to recover, the family enthusiasm gradually decreases, and deception is overwhelming. When this situation is prolonged, they considered the medical stuff responsible for this situation. Also they often think that if they knew from the beginning about the struggle of their newborn they would not have insisted on keeping him alive at all costs.[15] The ethical can helps in these cases[16], fact described by the art 185 of the 95 / 2006 (improving clinical standards and practice patterns in order to provide quality of medical services in order to enhance patient satisfaction).

Particular situations of informed consents:

1. abandoned child (advisers of arbitration, in according with article 17 of Law 46/2006

2. parents that can't be found in proper time (advisers of arbitration, in according with article 17 of Law 46/2006

3. single mother (if one parent consents and the other not, the medical act can be done)[17]

4. minor mother (the mother can understand information about her child, but in this case it involved the presence of the social services)[18]

14, 16 Stoicescu Silvia Maria şi col. "*Aspecte etice in sectiile de terapie intensive neonatal*", Ethical issues in neonatology , Ed Gr.T. Popa, 2011

15 Stamatin Maria, Paduraru Luminita, *Particularităţi etico-medicale în îngrijirea nou-născutului cu risc vital*, Romanian Journal of Bioethics, vol. 7, 2009

17, 18, 19 Janet M Rennie, Textbook of Neonatology , Elsevier, Churchill Livingstone, 2005

20 Janet M Rennie, Textbook of Neonatology, Elsevier, Churchill Livingstone, 2005

5. mother with mental illness (social services must be involved)[19]

6. the parents does not agree with the medical procedures or treatment, but the child needs special treatment to be done

7. the parents with religions believes that do not allow the use of biological products for their child (eg: blood).

The child and adolescent period:

According to the law, a minor has no capacity to consent to an intervention. This can be done without the authorization of its legal representative, other authority or other persons designated by law. Minor opinion will still be considered. In medical practice, the children interest should play an important role.[20, 21,22]

Children and teens can participate to the process of taking the decisions concerning the methods of prevention, diagnosis and treatment when these concern them directly. (Declaration of promoting patients' rights in Europe, Amsterdam, 1994 – Chapter 3 / Law 46/2003, article 18). The role of parents is that of the guidance, of the counseling and protection. Children are defined as lacking in autonomy. But there is no consensus about the determination of their capacity to understand their disease or treatment. Therefore bioethics experts state that the decision involving older children and adolescents should include their opinion besides their parents. Like informed consent, obtaining the views of the child must be an interactive process.

According to article 19 of Law 46/2003, the persons that are not able to express their will cannot be used for scientific research. The exceptions consist in the obtaining of the consent from the legal representative, when the research is done in the interest of involving children. Pediatric research can be performed only in therapeutic purposes, for the advantage of the subjects, with the consent of parents or their legal represents. Also the child consent is also necessary.

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21 Saigals, Stoskopf BL FennyD, Perception of health status an quality of live of extremely low birthweight survivors, Clin Perinatol 27:403, 2000

22 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,Oviedo, 4.IV.1997

Exceptions:

Exceptionally, children may express their consent (up to age 18 years), according to the art. 9 of Law 95/2006 on healthcare reform, Title XV, a civil liability of medical personnel and the article 650 of Law No. 95/2006 on healthcare reform in the absence of parents or legal representative in the following cases:

a) emergency situations, when the parents or the guardian cannot be contacted, and the minor has necessary discernment to understand the medical situation

b)diagnosis-related medical conditions and / or treatment of sexual and reproductive issues, at the express request of the minor aged over 16 years.

According the article 15 of Law 46/2003, the lack of consent does not mean the lack of appropriate emergency medical care. If the patient requires emergency medical intervention, the legal representative's consent is not required.[4] The article 17 of the same law highlights the active role of an arbitration panel specialized in assessing the patient's interest.

In genetics:

Genetic is the science which studies parents – followers compartmental, biochemical and physical structures transmission. Genetic information is transmitted through generations. The sum of gene and hereditary information create so named genome.

Genome is made by all genes and hereditary information. UNESCO declared genome as humanity common en heritage, and its research is entire humanity responsibility. According to convention of human rights and biomedicine, Oviedo, 4.IV.1997, ratified by Romania through the Law 17/2001, the human is more than its own genetic program.

As following:

-its forbidden any kind of discrimination to a person as a result of its genetic en heritage (art. 11)

-its forbidden to asses predictive tests for genetic diseases or tests for detecting a disease provoking gene in a subject, to asses a predisposition or

a genetic susceptibility for a certain disease, except for health or medical research reasons, and under the pertinent genetic advice (art. 12)

-any intervention which will produce human genome modification can be performed only with preventive, diagnostic and therapeutic purpose, and only in case that its is no modification in the descendants genetic genome (art. 13)

-the utilization of medical assistance techniques in procreation will not be allowed to select gender, with the exception of the situations in which important gender disease must be avoided (art. 14)

Assisted medical reproduction might be realized through gametes donation, in vitro fertilization, by a carrying mother or by combinations of those 3 methods. Those techniques are performed with an informed consent, but there are some juridical issues:

-selling ovules, uterus renting for child birth are forbidden by the New Civil Code art. 66.[23]

-genetic abuse in order to allow good genes recombination and stopping bad ones recombination (eugenics) is forbidden by the New Civil Code art. 62.[24]

Cloning is a process in which is obtained an identical copy of the original organisms. There are 3 types of cloning:

1.embryonic cloning

2.adult DNA cloning (reproductive cloning)

3.therapeutic cloning (biochemical cloning)

One of European conventions which forbid cloning is the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998. In Romania human cloning is forbidden despite informed consent, by the law no. 17 of 22 of February

23 art 62 New Civil Code :" (1) Nimeni nu poate aduce atingere speciei umane; (2) Este interzisa orice practica eugenica prin care se tinde la organizarea selectiei persoanelor; "

24 art. 66 New Civil Code " Interzicerea unor acte patrimoniale: Orice acte care au ca obiect conferirea unei valori patrimoniale corpului uman, elementelor sau produselor sale sunt lovite de nulitate absolută, cu excepția cazurilor expres prevăzute de lege. "

2001[25], by the New Civil Code, art 63, paragraph 2 (it is forbidden and intervention which will have as purpose the creation of identical genetic humans with other living or death human), and by the CMR Deontological Medical Code (art. 112 Experiments regarding human cloning are forbidden).

In donation and organ transplant:

Organ donation is the process by which some organs and tissues are extracted from one body and delivered to another body. Organ transplant involves some organ or tissue surgical removal from one person (donor) and insertion to another person, with the purpose of organ failure or absence replacement.

As a general rule, art. 19 of the Convention regarding human rights and biomedicine, Oviedo, 1997, it is stated in 2nd raw the obligation to an written informed consent. Additional Convention Protocol regarding human organ and tissues transplantation (Strasbourg 2002) states that the organs and tissues will not be collected from a clinical death person without its previous written consent or without authorization due to legislation, and the collection will not be performed in case that the patient has a previous objection.

In the art. 68 of the New Civil Code it is stated the obligation of patient's consent, and the possibility that the donor might reconsider it (1st raw), in the same time it is stated that pediatric organ collection is forbidden, with the exception of the cases stated by the law, in the 2nd raw. In the same time Law no. 2 from January 1998, regarding human tissues collection and transplantation 1998 (now abrogated) stated donor and receiver consent, statement which are kept in the actual legislation (Law 95/2006, Title VI).

A. Human organ and tissue collection might be performed from:

1. A living major person[26,27]

-only with donor written informed consent

-in therapeutic purpose

25 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,Oviedo, 4.IV.1997

26, 27 Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998

-if there are not any danger to donor life

-the donor may reconsider its informed consent but only till the time of collection

-in case that there are not available organs and tissues from a deceased person

-in case that there is not an alternative efficiency comparable therapeutic option

2. A living pediatric person [28]

The law forbidden organs and tissues collection from living pediatric person. As an exception, stem cells collection from haematopetic medular and periferic origin might be collected:

-above the age of 14, only with the pediatric patient consent and with the legal protector, parent, legal tutor or doctor written informed consent

-below 14 years old, collection might be performed with legal protector written informed consent

-written informed consent is expressed in front of the County or Backrest Tribunal President

-it is obligatory to perform an inquiry by the competent tutelary authority .

Pediatric person refusal abrogates any collection.

3.Deceased person:

According with Law 95/2006, Title VI regarding human tissue collection and transplant is performed:

-only with written informed consent of at least one major member of the family, a relative or an legally authorized person

-without written informed consent of at least one major member of the family, if, during patient's life, the deceased person already expressed his option in donation favor, legalized by a notary commitment or by enrollment in the National Repertoire of organ, tissue and cells donation

- the collection could not be performed in any case, if, during his life, the deceased person already expressed his option against donation, by an act notified by its own family doctor or by enrollment in the National Repertoire of organ, tissue and cells donation refuse.

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28 art 144 , Law 95/2006, Title VI regarding human tissue collection and transplant

B. Human tissue and organ transplant[29]

-only with therapeutic intention

-with receiver informed consent

-in case that the receiver has no possibility to offer his consent, the written consent might be given by a family member or by the legally authorized person

-without previous written informed consent if, due to unexpected objective facts, the family member or by the legally authorized person could not be contacted, and the delay might have as consequence the receiver death

-for pediatric patients or the patients without discernment, the written consent will be provided by the parents or by the legally authorized person

Romanian Orthodox Church expresses its disapproval regarding the term "presumed consent" (by normative acts), because contravene all moral Christian-Orthodox principles, abolishes the principle of self-offering and brotherhood love contented in the informed consent, and in the same time exclude the family role in the case of decease or clinically death persons without a clear consent expressed during their life. Romanian Orthodox Church appreciates that organ collection and organ donation acceptation has a moral value only when it is performed informed, consciousness and with altruisms.[30]

In scientific research and clinical studies:

European and International Conventions are:

-Declaration regarding Informed Consent is prerequisite and obligatory for research and patients rights in Europe, Amsterdam, 1994 (chapter 3)

-International Conference on Harmonization good clinical practice from 10th of June 1996 (sub chapters 4.8.1-4.8.15)

-World Medical Association Declaration of Helsinki, June 1964 regarding ethical principles for medical research which involves human subjects (last modification Tokyo 2004)

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29 art 149,150,151,152 Low 95/2006, ,Title VI regarding human tissue collection and transplant

30 Romanian Journal of Bioethics, vol. 6, no. 3, July - September 2008

-Directive 2001/20/CE of European Council and Parliament from 4th of April 2001 of European Members States law power and administrative papers connection regarding clinical good practice in cases of clinical studies for human use drug products, etc.

Romanian legislations:

-Law no. 46/2003, patient's rights law (art. 19)

- New Civil Code (art. 61, 67)

-The Code of Deontology of the Medical College in Romania (art 90,91,98,100,101,109)

-Guide CPMP/ICH/2711/99 regarding drug clinical investigation in pediatric population, etc.

It shows that:

-human interests has to prime in front of science and society interests

-informed consent has to be signed by patient or by legal representative

-patient informed consent has to respect all legal aspects

-vulnerable persons, susceptible to have the informed consent signed under pressure (prisoners, military population) has to benefit to a certain protection

-human subjects participation in research can be performed only voluntarily and only after adequate information was provided regarding the scope, research methods, anticipated risks and benefits

-the subjects has to be informed that they could withdrawn from the research anytime

-for human verification of the efficiency of a treatment or diagnostic method the voluntary consent condition of the subject has to be rigorously respected

-in cases of pediatric subjects, the consent will be obtained from the parents or legal representative , being necessary the subject acceptation for research participation

-in cases of willing or commitment incompetent or incapable persons, the consent will be obtained from family or legal representative

-informed consent application has to be at the 6th grade education level (maximum 8th grade), to contain approximately 2000 words, but not more that 10 pages.

Legal liability of physicians and informed consent

Legal liability (criminal, civil, disciplinary, etc..), one of the forms of social responsibility, defines a person's ability to discharge fully its obligations as a result of committing an act or an illicit fact which violates the rules of positive objective and therefore could be subject to legal sanction for his actions or inactions. It means the possibility to apply a legal sanction, imposed by a magistrate (full court) as representative of society, for an illicit fact.[31]

It is very important to determine if patient's rights are enshrined in principle only, or if there is a legal framework necessary for compliance. Article 37 of Law no. 46/2003, patient rights law shows that non-compliance by healthcare professionals to patient data privacy and confidentiality of medical as well as other rights stipulated in this Law shall make the patient, as appropriate, disciplinary, administrative or criminal, according to law. " It gives such a legal and imperative character to patient rights, lifting their status beyond simple principles.

Regarding Informed consent appear on the following aspects:

-lack of informed consent with reference to the medical question (often surgical) of the patient's clinical observation sheet

-not fallowing the exactly procedures in diagnostic and therapeutic techniques and resources covered by the consent given

-performing procedures other than those authorized

-failure to comply with the conditions provided by law for obtaining consent

When we talk about medical liability must be analyzed and the conditions to undertake this responsibility. The relationship of medical law, the rule is that the obligation is an obligation of medical means, doctor is required to make all diligence efforts to cure patients, and in case of one negative outcome in the process of healing the patient, is not automatically equivalent with the failure practice. In this respect are the provisions of art. 10 of the Code of Medical Deontology CMR, according to which " doctor will not guarantee cure of the disease for which the patient has addressed". Medical fault is determined, most often by the ignorance of the physician in their diligence

31 V. Iftenie, *Medicina legală*, Medical Sciences Publishing House, Bucharest, 2006

obligations of which must underlie every act or fact that it fulfills its relationship with the patient. In the wrongful act that caused patient harm could have been avoided in the doctor practice with the diligence required by law, he will be liable to disciplinary, civil or criminal liability thereof, depending on the circumstances of the offense and the severity of an injury.[32]

Obtaining valid consent requires the patient to be actively involved in solving problems, as much as he wants. Even if the patient is prone to make decisions in accordance with medical opinion, he should be actively involved in judging the consequences that would result from its decisions.[33]

The illegal fact of the doctor is represented by any conduct which he has, while exercising the medical profession, contrary to existing rules (rules that would subsume the objective law, as well as the customary moral, social life), through which injury has occur to the patient. In order to retain the civil liability of the physician in terms of condition relating to the illegal fact should be involved with a failure of following the obligations by the professional, either by default or by performing them improperly.[34]

If there is consent of the patient, obtained in legal terms, prior to committing the illicit fact, and acted under that authorization doctor in a default, which provided, including the possibility of damage causation, of illicit fact the nature of the offense is removed and with it, is removed and medical liability (non fault clause). The consent given in such cases is not in favor of the injury. He authorizes the deployment of a medical act, committed by someone else that can cause them damage, before this can occur.

Informed consent does not exclude doctor liability for professional negligence when during the medical act occur mistakes (article 13 of Code of Medical Deontology CMR - Expression of the patient's informed consent for medical treatment does not remove responsibility for any professional misconduct).

Committing by the doctor a guilty of illicit facts that produces a negative effect of patient, leads to *CIVIL LIABILITY FOR DAMAGE DUE TO*

32 Georgiana Tudor, *Răspunderea juridică pentru culpă și eroarea medicală*, Ed. Hamangiu, 2010

33 International Center for Health Law and Ethics School of Law, University of Haifa, Israel Department of Bioethics, *Informed Consent*, Editor: Amnon Carmi, Coordinator: H. Wax

34 Georgiana Tudor, Raspunderea juridică pentru culpa si eroarea medicala, Ed Hamangiu, 2010

MISFEASANCE OR NONFEASANCE. Those damages can be assessed as moral (non-patrimonial), or patrimonial. What ever their nature may be, the compensation is patrimonial.

Civil liability out of contract

According to the Civil Code, the essential conditions for the validity of an agreement are: capacity, consent, object and cause. In some special situations, such as plastic surgery and dental prosthetics, are guaranteed the benefits of medical treatment and this time the obligation is of result. It can be opposed only if the doctor was formulated in express. The obligation breached is an actual obligation, established by an existing pre-contract, valid agreement between the injured and one who has violated a contractual obligation.[1] Patient consent is deemed given for achieving results.

CRIMINAL RESPONSIBILITY is defined as the legal position of criminal justice coercion, that occurs as a result of the offense (the fact which represent a social danger, doing the guilt-by intent or negligence, and punished by the criminal law). The doctor is criminally liable whenever through his activity commits one of the facts provided by the Romanian criminal law, unless in the situations in which is included one of the cause that removes any of the criminal nature of the fact. Treating a patient without his consent is an offence. Such talk malpractice by omission (when the informed consent is not before performing a medical act). Regarding autonomy principle, any person may have his own body as he sees fit and any medical act which it aims requires the existence of prior informed consent. There is an exception, that of emergency, when the patient's life is threatened and that he can not agree and is not accompanied by a person with legal quality to allow him to do accept instead of him. Conform with article 155 of Law 95/2006, Title VI, "extraction or transplant of organs, tissues and / or cells of human origin without a consent given under this title shall constitute an offense and punishable with imprisonment for 5-7 years". Patient's consent can not authorize actions directed against life and bodily integrity. Moreover, in Romania euthanasia is forbidden by law (art 121 of Code of Medical Deontology CMR– euthanasia

to be strictly forbidden, the use of substances or methods in order to cause the death of a patient, regardless of severity and prognosis, even if it was urged by a perfectly conscious patient).

In conclusion, science is in the service of humanity, dignity and human rights (World Congress of scientists in Budapest, 1999). The right to life and health represent the meaning of all other human rights. Sovereign rights of patients against the body and his being is based on the principle of autonomy of will. From it derives the right to informed consent. Informed consent principle aim is to enable the patient to weigh the advantages and disadvantages of covered medical care, so they can make a rational choice between accepting or refusing. Also, informed consent can reduce error, negligence, coercion and lies and encourages an attitude of self-criticism of the performer.[35] The justice guards the observance of these principles, the primacy of human beings is the foundation of legal norms on human rights related to biomedicine.

35 International Center for Health Law and Ethics School of Law, University of Haifa, Israel Department of Bioethics, *Informed Consent* ,Editor: Amnon Carmi ,Coordinator: H. Wax