# Termo de Consentimento Informado: a Visão dos Advogados e Tribunais *

## *Informed Consent: The Understanding of Lawyers and Courts*

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**RESUMO:**
Godinho AM, Lanziotti LH, Morais BS – Termo de Consentimento Informado: a Visão dos Advogados e Tribunais.

***JUSTIFICATIVA E OBJETIVOS**: Nos últimos anos, houve no Brasil um aumento do número de ações judiciais em função de erros médicos, devido, sobretudo, a uma conscientização cada vez maior da população em busca de qualidade no atendimento que lhe é oferecido. De acordo com a Constituição da República de 1988 e o Código de Defesa do Consumidor, o médico não pode submeter o seu paciente a tratamento ou procedimento terapêutico sem antes obter seu consentimento. O objetivo deste artigo foi conferir aos profissionais da medicina uma visão jurídica acerca do universo do consentimento informado.*

***CONTEÚDO**: O texto aborda o histórico, conceitos e fundamentos do Termo de Consentimento, requisitos para validade, a saber: capacidade do paciente, voluntariedade, compreensão e prestação das informações relevantes, assim como circunstâncias que dispensam o consentimento.*

***CONCLUSÕES**: Por meio da assinatura do Termo de Consentimento Informado o paciente declara estar ciente da natureza da intervenção médica e dos correspondentes riscos, assumindo-os livremente. Espera-se com este artigo tornar a classe médica mais consciente dos aspectos legais que giram em torno do tema, para que, a partir daí, sejam evitados os equívocos que costumeiramente transferem a sagrada relação médico-paciente dos consultórios e hospitais para os fóruns e tribunais.*

**Unitermos**: *ÈTICA MÉDICA: termo de consentimento; consentimento informado.*

**SUMMARY**
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***BACKGROUND AND OBJECTIVES:** An increase in malpractice lawsuits has been seen in Brazil over the past several years, mainly due to higher awareness of the population regarding the quality of the medical care provided. According to the 1988 Brazilian Constitution and Consumers' Defense Code, physicians cannot subject patients to any treatment or surgical procedure without proper consent. The objective of this article was to provide medical professionals the legal understanding on informed consent.*

***CONSENTS:** This report focuses on the history, concepts, and fundaments of the informed consent, and validity requirements such as: capacity, voluntariness, and understanding by the patient, and providing relevant information, as well as the circumstances in which the informed consent is not necessary.*

***CONCLUSIONS:** Signing an informed consent is a statement, by the patient, that he/she is aware of the nature of the medical intervention and corresponding risks, and he/she freely accepts those conditions and risks. With this article, we hope the medical community will be more aware of the legal aspects involving the matter to avoid misunderstandings that commonly transfer the sacred physician-patient relationship from medical offices and hospitals to the courts.*

**Keywords:** MEDICAL ETHICS: informed consent.

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## *Informed Consent: The Understanding of Lawyers and Courts*

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### INTRODUCTION

Informing patients on the diagnosis, treatment, or therapeutic procedure necessary and how they should be presented so patients can understand are major sources of concern in the medical community. With proper information, the patient has the autonomy to decide whether he/she should accept or not the treatment offered. Thus, the objective of the physician is not only the fulfillment of the moral obligation to inform the patient everything that is happening to him/her, but also to free him/herself from civil responsibility in case of treatment failure if he/she is not responsible for such. An increase in malpractice lawsuits has been seen in Brazil over the last several years. The numbers show a growing awareness of the population in search of quality of acre.

After the advent of the 1988 Constitution [1] and Consumers' Defense Code [2] (Law #8,078 of 1990), physicians were no longer allowed to subject patients to treatments or surgical procedures without prior consent.

One of the first cases known of a lawsuit between patient and physician dates back to 1767, in England. Two physicians, Dr. Baker and Dr. Stapleton, without prior consent from their patient, Mr. Slater, removed a bony callus from his leg, after he recovered from a fracture, due to imperfect consolidation [3]. This procedure caused another fracture in the affected bone. Disillusioned with the physicians, the patient sued them on the grounds of lack of expertise and imprudence during the procedure, as well as not informing him on the consequences of that treatment. He also stated that, during the procedure, he asked the physicians to interrupt it complaining about their conduct. The English court decided against the physicians, indicating in the sentence that they broke the contract governing the physician-patient relationship.

Despite of this report, the expression "Informed Consent" (IC) appeared at the end of the XX Century, with very few information on this practice before the 1960s [4].

The fundaments of the IC are implicit in the Universal Declaration of Human Rights [5] (1948), which can be seen in Articles 1 – *"all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood"*; 3 – *"everyone has the right to life, liberty, and security of person"*; and 5 – *"No one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment"*. The Nuremberg Code [6] (1947) mentions "voluntary consent". The Declaration of Helsinki [7] (1964) consecrated the expression "informed consent".

Therefore, the expression "informed consent" was adopted worldwide. It is widely accepted that the patient is responsible for deciding, based on information given by the medical team, whether he/she intends to undergo the proposed treatment or not. Thus, some important aspects on this subject should be cleared, which can contribute to decrease the constant lawsuits against physicians secondary to the lack of knowledge on the requirements that validate legally the Informed Consent (IC). Besides the requirements necessary for the validity of the IC, other aspects, such as the level of the information given to the patient and the situations in which it is not necessary, will also be discussed, keeping in mind that this discussion only refers to medical interventions performed when the individual is alive and, therefore, does not includes the *post morten* disposition of the body or organs.

### Informed Consent: concept and fundaments

Among the most elementary legal principles, self-determination, especially relating to "private autonomy", which gives individuals the right to choose whether to undertake or not specific actions of civilian life, is paramount, i.e., such autonomy consists on the possibility that individuals are allowed to make free and conscious decisions about themselves and their possessions [8]. Therefore, this doctrine is a corollary for the freedom of individuals to command their interests according to their desires. Thus, it can be said that, in the physician-patient relationship, the patient should decide whether to accept or refuse any treatment or medical intervention, based on the information given to him/her about the risks and the procedures proposed. The IC is mandatory, and it should be written to define, in details, the responsibility of probable failures, and should be used regardless of the extension of the intervention.

Although Brazilian law does not mention the "informed consent", the notion that the patient is free to decide whether or not to accept any medical treatment or intervention has been consecrated. Legislative and statutory precedents confirm this statement: here we should mention Article15 of the Civil Code [9], which establishes that no one can be intimidated to undergo, at the risk of their own lives, any medical treatment or surgical intervention; The Consumers' Defense Code [2] also indicates the need of proper information, especially in its Article 14, which states that those providing a service are responsible for not given enough and adequate information; Finally, the roots of the IC can be found in the Resolutions of the Federal Medical board (# 1,081/82, 1,358/92, and 1,890/09), of the National Health Council ((# 196/96), and the Medical Ethics Code, especially in Articles 46 (forbids any medical procedure without prior consent, except in cases of imminent danger to one's life), 56 (forbids the physician, except in case of imminent risk to one's life, to disrespect the right of the patient to freely decide whether or not to accept diagnostic or therapeutic procedure), and 59 (the physician has the obligation to inform the patient the diagnosis, prognosis, and the risks and objectives of the treatment, except in cases when direct communication with the patient can be harmful, in which case the information should be given to the legal guardian). Legally, the IC is also a consequence of the good-faith that should guide every contractual relationship, including that between physicians and patients, imposing to both of them, especially the former, and obligation to give the other part, with transparency and loyalty, all relevant information.

Since it is not legally foreseen in Brazil, its concept becomes that of an interpreter. However, it is possible to obtain from Law # 3/2001 of the Autonomous Community of Galicia, Spain, an encompassing concept of informed consent, which would be the expressed acceptance of the patient, in writing, in face of the adequate information received, of the diagnostic or therapeutic procedure proposed that affects him/her and that carries with it important, well-known, or considerable risks. The law itself goes on to say that the informed consent is both a right, of the patient, and an obligation, of the physician.

The IC represents an authorization for an intrusion on the physical integrity of the patient, which revokes any illegalities in the behavior of the physician, unless it characterizes ill professional conduct, in face of investigating guilt. However, it should be considered that the patient is the weak figure in the relationship with the patient, precisely for ignoring the technical aspects of medicine. Since the IC is an expression of the will of the patient, it is required that he should be completely aware of the nature of the proposed procedures and inherent risks to, if this is the case, authorize said procedure. This is done by signing the Informed Consent, which should contain, in a language accessible to the patient, the information required to help the individual make a decision. By signing the IC, the patient declares to be aware of its contents and assumes, of his/her own free will, the risks indicated.

**Requirements for the validity of the Informed Consent**

To proclaim the validity of the IC, the following requirements should be fullfiled:

a) capacity of the patient: According to Article 5th of the Civil Code, capacity is achieved at 18 years of age or by emancipation in the cases described by the same article. However, occasionally the age factor is not enough to assess the capacity and other parameters, according to the notion of discernibleness of the agent, should be considered. For this reason, Articles 3rd and 4th of the Civil Code node only contemplate the protection of under aged individuals, but also qualify as incapable individuals with mental infirmities or deficiencies, and those addicted to alcohol or other drugs, even foreseeing the hypothesis of temporary incapacity, such as that of patients in coma or in a state of shock. Regarding specifically medical relationships, the list of incapable individuals described in the above mentioned articles only does not contemplates the spendthrifts, since their condition of being wasteful only prevents them from making decisions regarding patrimonial matters, which is not the case of when the life, health, or physical integrity of the patient is at stake. Therefore, for all others, their legal guardians, i.e., parents, tutors, curators, should give consent. Observe that, in case of incapable individuals older than 18 years, the wife or husband (or partner, in case of common law marriage) will be the legal guardian, unless they are judicially separated or divorced, according to Article 1,775 of the Civil Code. When those individuals are not available, parents or descendents will be responsible for the decisions.

A last aspect regarding incapacity should be mentioned: "capacity to give consent". The thesis that the consent of a legal representative should only be accepted when the incapable individual is not intellectually or psychologically capable to comprehend the extension and severity of the case is increasingly more prevalent [10]. One should take into consideration that if an objective analysis of the norms of the Civil Code on capacity and incapacity seem enough to validate patrimonially-related actions, they do not provide a clear answer regarding the possibility of making medical decisions because they do not fulfill the *"variation of intellectual, emotional, and volitional capacities of underage individuals and psychiatric patients nowadays"* [10]. Therefore, one should appeal to the notion of *discernment* of patients regarding the *"capacity to make a rational decision on the risks and sacrifices of their legal patrimony"* [11]. When thinking on the protection of a legal patrimony, such as life, health, and physical integrity, the owner of those rights has the legal right of making a choice and, in cases of discrepancy between the will of the incapable individual and his/her legal representatives, it is up to the Legal System to resolve the controversy.

b) voluntariness: it is not enough to merely assess the capacity or judgment of the patient; it also fundamental to determine whether the individual gives consent freely and spontaneously, i.e., without deception or coercion; otherwise, the consent or statement will be flawed if it results from deceit, ignorance, or false allegations made with the sole purpose of deceiving the patient, as well as in the cases in which the patient gives

consent due to physical or psychological intimidation. For all those cases, Article 171 of the Civil Code indicates the act is not valid, which makes the physician responsible.

c) understanding: one cannot deny that the patient is not in a favorable position in relationships with physicians, since he/she is a lay person. Here, the notion of *hypo sufficiency* of the Consumers' Defense Code, whose Article 6th paragraph III states that the information given to the consumer should not only be adequate and clear, but also specify the risks of said service, prevails.

One can only speak about deliberate will when the patient has clear understanding of the terms of the IC, which should be as transparent as possible. Thus, one of the requirements for the validity of the IC, according to Resolution 196/96 of the National Health Council, is that it its language should be accessible, clear, and non-biased, therefore preventing the patient to undergo any treatment without satisfactory explanations of all the risks he/she will be taking.

The vocabulary used in the IC, characteristic of the medical field, often needs to be explained to the patient for proper understanding. The structure of the text is also important. Long words, phrases, or paragraphs hinder understanding of the ideas presented. Besides, the information given to the patient regarding his/her disease should be explained in a simple, comprehensive manner, and the use of abbreviations and scientific terminology whose meaning is not explained is not allowed.

A recent study [12] showed that individuals higher schooling, frequent readers, with easy access to the Internet, and better salaries have better understanding of the IC. It also showed low rate of understanding of the word consent, even when clear, easy to understand language was used, and this understanding was not age– or gender-related. Therefore, the IC should be written and presented in a way that allows the highest degree of understanding possible for anyone, even the individual most distant from this reality has. The text should be adequate to the intellectual level of the population it is aimed at; in Brazil, it should be aimed at those with elementary education [12]. The physician should seek and effective interaction with patients, observing the conditions and limitations of each one, explaining every aspect of the IC, so it can be a source of insurance for everyone.

d) giving relevant information: the reach of the IC is its most delicate aspect. In the United States, it has been shown that physicians have been "hyperinforming" their patients with the sole objective of preventing possible responsibility, which negates the intention and real function of the informed consent in the physician-patient relationship. Taking the notion of the IC to extremes is undesirable, since any useless or exaggerated information can contribute to deform the opinion of the patient.

Thus, within the scope of informing, the following should be present: name and last name of the patient and physician; name of the procedure; explanation of the benefits expected from said intervention and the consequences of not giving consent for it, respecting individual circumstances (the medical history of the patient, state of health, and presence of aggravating factors, such as allergies or other diseases, among other); possible complications, mortality, and sequelae; treatment alternatives compared to the proposed treatment; explanation of the type of medication required for the intervention and its risks; cost of the treatment (this is not necessary only if it has been predicted in another document, such as a contract); contraindications; possibility of suspending the consent at any time before the intervention; patient satisfaction with the information received as well as resolution of all doubts; signature of the physician, patient, and witnesses, if any are present, besides their initials on all pages. It also seems convenient to indicate the possibility of verifying other risks, although unpredictable, which will give the patient the dimension that the information given to him are related to regular consequences of the treatment.

The IC can also contain, on a separate paragraph, authorization to obtain pictures, videos, or graphic records before, during, and after the intervention to spread the results or iconography in Medical Journals and/or in the scientific field.

Still regarding the duty to inform, it is fundamental to establish verification of bilateral good-faith: the same way it is the obligation of the physician to give all the necessary explanations to the patient, the patient should also give the physician all the information he/she can that could interfere with the efficacy of the treatment. This certification of veracity of the information provided can be at the end of the Informed consent, declaring that the patient, during the anamnesis and throughout the process up to that point, has been truthful with his physician. Omission of relevant data by the patient can reverse the perspective delineated so far, and it can make the physician to make an undesirable mistake, which can make him responsible if malpractice, due to negligence or incompetence – which might occur, for example, if he does not request a routine exam because he trusted the veracity of the information given by the patient.

Summarizing, the non-observance of any of the requirements listed does not allow one to call it an informed consent, which might incur in civil and penal responsibility of the physician, may it be by the damage caused to the patient or by non-consented intervention on his physical integrity. In those cases, even in the absence of physical damage, at least the presence of an illicit action against the right to self-determination of the patient could be proven.

## Circumstances in which the Informed Consent is not required

There are exceptional circumstances that allow the physician prompt action regardless of the concordance of the patient or legal representatives. In case of imminent life risk or severe and irreversible injury, when the patient is not capable to give consent, the urgency to attempt to save his/her life or physical integrity justifies immediate medical intervention. Article 45, 56, and59 of the Medical Ethics Code, mentioned before, legitimate this conduct.

Besides, if the patient, in situations of intermediate risk, is unable to give consent and a legal representative cannot be

found or is not available to authorize the intervention, the physician is entitle to take immediate action to preserve the physical integrity of the patient.

In the situations described, one cannot talk about illegal action, may it be in the civil, penal, or administrative sphere. The physician is protected by legal rules that exclude illicit actions – in this case, the need and the regular practice of a right, supported by Article 123 of the Penal code and 188 of the Civil Code.

## CONCLUSION

The Informed Consent, which pays relevant tribute to the right of the patient for self-determination, is a relatively recent, but widely accepted, phenomenon. By signing the IC, the patient states he/she is aware of the nature of the medical intervention and corresponding risks, accepting them of his/her own free will.

However, to clearly state the will of the patient, the IC should contain: the capacity of the agent, with special focus on the "capacity to consent"; voluntariness, to impose the will of the patient free of biases; understanding, which allows the patient to judge the intended intervention, to which he/she can give consent or not; and finally, provide fundamental information to allow the patient to make a decision freely.

Exceptionally, there are occasions in which the physician can, legally, take action without resorting to the IC. These are cases in which urgency is paramount to save the life and physical integrity of the patient, which allow immediate medical intervention without characterizing an illegal action in any judicial level.

The objective of those notes was to provide medical professionals the legal view of the informed consent. We hope to have achieved the fundamental scope intended when designing this article: to make medical professional more conscious of the legal aspects surrounding the matter to avoid the misunderstandings that commonly transfer the sacred physician-patient relationship from offices and hospital to the courts.

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**RESUMEN:**

Godinho AM, Lanziotti LH, Morais BS – Término de Consentimiento Informado: La Visión de los Abogados y Tribunales.

***JUSTIFICATIVA Y OBJETIVOS****: En los últimos años, se dio en Brasil un aumento del número de demandas judiciales en función de los errores médicos, principalmente, a causa de una concientización cada vez más fuerte de la población que busca la calidad en la atención que le ofrecen. De acuerdo con la Constitución de la República de 1988 y el Código de la Defensa del Consumidor, el médico no puede someter a su paciente a un tratamiento o procedimiento terapéutico sin que antes tenga su autorización. El objetivo de este artículo fue darles a los profesionales de la medicina una visión jurídica acerca del universo del consentimiento informado.*

***CONTENIDO****: El texto aborda el historial, los conceptos y los fundamentos del Término de Consentimiento, los requisitos para la validez, a saber: capacidad del paciente, voluntariedad, comprensión y prestación de las informaciones relevantes, como también las circunstancias que no necesitan ese Consentimiento.*

***CONCLUSIONES****: A través de la firma del Término de Consentimiento Informado, el paciente declara tener conocimiento de la naturaleza de la intervención médica y de los correspondientes riesgos, y los asume con plenitud de conciencia. Se espera que con este artículo, la clase médica esté más consciente de los aspectos legales que están en torno al tema, para que, a partir de ese momento, se puedan evitar las equivocaciones que a menudo hacen llevar la sagrada relación médico-paciente de los consultorios y hospitales, hasta los tribunales.*