

**RESEARCH**

## Informed consent: impact on court decisions

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**Abstract**

The informed consent form is essential in the physician-patient relationship. To evaluate its impact on court decisions, we conducted a retrospective study of 70 civil suits involving surgical and non-surgical aesthetic medical procedures with an informed consent form signed by patients. The cases, judged between 2014 and 2016, were selected from Brazilian courts websites and classified into two groups: acquitted (51%) and convicted (49%) doctors. In the first group, 39% of acquittals were based on the proper presentation of the informed consent form, whereas in the second 50% of the professionals were convicted for not including the document. The informed consent thus stands out when judging medical errors, and the duty to warn is one of the pillars of the professional liability and, when neglected, becomes a substantial factor for their conviction.

**Keywords:** Informed consent form. Duty to warn. Esthetics. Damage liability. Medical errors.

**Resumo****Termo de consentimento informado: impacto na decisão judicial**

O termo de consentimento informado é fundamental na relação jurídica entre médico e paciente. Visando avaliar seu impacto na sentença judicial, realizou-se estudo retrospectivo de 70 processos de responsabilidade civil envolvendo procedimentos médicos estéticos cirúrgicos e não cirúrgicos com termo de consentimento assinado pelos pacientes. Os casos analisados, julgados entre 2014 e 2016, foram selecionados nos sites dos tribunais brasileiros e classificados em dois grupos: médicos absolvidos (51%) e condenados (49%). No primeiro grupo, 39% das absolvições se embasaram na apresentação adequada do termo de consentimento informado, enquanto, no segundo, 50% dos médicos foram condenados por não o ter incluído. Portanto, o termo de consentimento informado se destaca nos julgamentos de erro médico. O dever de informar é um dos pilares da responsabilidade civil desse profissional e, quando negligenciado, constitui fator substancial para condenação.

**Palavras-chave:** Consentimento livre e esclarecido. Responsabilidade pela informação. Estética. Responsabilidade civil. Erros médicos.

**Resumen****Término de consentimiento informado: impacto en la decisión judicial**

El formulario de consentimiento informado es fundamental en la relación jurídica entre médico y paciente. Para evaluar su impacto en sentencias judiciales, se realizó un estudio retrospectivo con 70 procesos de responsabilidad civil relacionados con procedimientos médicos estéticos quirúrgicos y no quirúrgicos con el formulario de consentimiento firmado por los pacientes. Los casos analizados, juzgados entre 2014 y 2016, fueron seleccionados en los sitios web de los tribunales brasileños y clasificados en dos grupos: médicos absueltos (51%) y condenados (49%). En el primer grupo, el 39% de las absoluciones se basaron en la presentación adecuada del formulario de consentimiento; en el segundo, en el 50% de los casos se condenaron a los médicos por no incluir este documento. Por tanto, el formulario de consentimiento informado se destaca en los juicios por error médico. El deber de informar es uno de los pilares de la responsabilidad civil del médico, y su incumplimiento constituye un factor sustancial de condena.

**Palabras clave:** Consentimiento informado. Deber de advertencia. Estética. Responsabilidad civil. Errores médicos.

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The Consumer Protection Code (CPC)<sup>1</sup> innovated the relationship between doctor and patient by characterizing the former as a service provider and the latter as a customer. This novelty emphasized the professional liability, wherein the duty to warn predominates, as expressed in the following articles of the code:

*Article 6. The following are basic consumer rights:*

(...)

*III – Adequate and clear information on different products and services, along with the correct specification of their quantity, characteristics, composition, quality, incurring taxes, prices, and the risks they pose;*

(...)

*Article 8. Products and services in the market shall not pose risks to consumers' health or safety, unless considered normal and predictable due to their nature and fruition, being suppliers hereby obliged to provide the adequate and required information on such risks at any time.*

(...)

*Article 9. Suppliers of products and services potentially harmful or hazardous to health or safety shall ostensibly and adequately inform consumers about hazards and harms, notwithstanding the adoption of other applicable measures pursuant to each case<sup>1</sup>.*

Supported by the constitutional principle of human dignity, patients may decide how they want to live their life, which includes any medical treatment. Thus, the patient also has autonomy in the elaboration of the informed consent form (ICF), when this does not harm the good practice or medical ethics with consequent damage to the treatment process. They may also revoke the document at any time before the procedure, without the consent of the professional, denoting ethical integrity, honesty and good faith in such relationship. Such principles are expressed in the Brazilian Federal Constitution, whose article 1, item III, defines human dignity as the foundation of the Republic, and whose article 5, item II, determines that *no one shall be obliged to do or refrain from doing something except by virtue of law<sup>2</sup>*.

The new Code of Medical Ethics (CEM)<sup>3</sup> follows the interpretation of the Brazil's Constitution, respecting the dignity of the human person regarding the patient's autonomy. Despite the changes incorporated, the new code maintained the proposal of this device<sup>2</sup> and of the CPC<sup>1</sup>, in order to prioritize the importance

of information. Comparing the current version of the CEM with a previous one, we note a certain change. The 1988 version, in article 46, prohibits the professional from *performing any medical procedure without the clarification and consent<sup>4</sup>* of the patient, whereas article 22 of the 2018 CEM prohibits the doctor *from ignoring the acquisition of consent on the part of the patients or legal representatives after clarifying them the procedure to be performed<sup>3</sup>*.

This change shows the importance of the duty to warn in the legal sphere, and Brazilian courts treat the issue with increasing rigor. However, it is not enough to declare verbally that the patient was informed, it is necessary to prove it with a signed document (ICF). According to the section XXI of Chapter I of the CEM in force, *in the professional decision-making process, according to their dictates of conscience and legal provisions, doctors shall accept the choices of their patients regarding the diagnostic and therapeutic procedures expressed by them, provided they are appropriate to the case and scientifically acknowledged<sup>3</sup>*.

Although two actors participate in the elaboration of the form, it is not a contract for the provision of services, but a one-sided legal act that does not provide this right to the doctor. It serves as a means of informing and validating the Civil Code itself, whose article 13 states that, *except for medical requirements, the act of provisioning one's own body is defended when permanent decrease of physical integrity matters, or when it is contrary to good customs*, as supplemented by article 15, which states that *no one can be forced to undergo medical treatment or surgical intervention when at risk of life<sup>5</sup>*. In the context of the civil law, the duty to inform lies in the obligation of the health professional to clearly and specifically explain the service that shall be provided to the patient, based on the principle of objective good faith in relationships of trust<sup>6</sup>.

These articles follow the same constitutional principles of autonomy and personal dignity of the ICF, but diverges in purpose. All research involving human beings require the document signed by the individual or group participating or by their legal representatives to authorize their inclusion in the study, following the guidelines and regulatory standards of the National Health Council<sup>7</sup>.

Given the significant increase in the number of cases against doctors after the CPC, it is imperative to investigate the real legal effectiveness of the ICF in the defense of these professionals.

## Method

We conducted a retrospective study<sup>8</sup> of Brazilian courts decisions issued between 2014 and 2016, obtained from court websites<sup>9</sup>. For our search we used the following keywords in Portuguese: “*cirurgia estética/termo de consentimento informado*,” “*procedimento estético/termo de consentimento informado*” and “*termo de consentimento informado em estética*.” We selected 70 decisions in which the ICF was properly applied, with the patient’s signature authorizing surgical and non-surgical aesthetic procedures. The law considers only written ICFs, and not those designated as verbal or not found.

With the collected data from the court decision, we analyzed the processes and reasons that led to the conclusion of each case. In the context of this research, the ICF is considered a cause of acquittal or conviction, with its variables “provided” and “not provided,” in addition to the causal link being absent/present; guilt being absent/present; ICF provided together with another reason; obligation of results. These last variables are grouped into “other.”

## Results and discussion

The sample of 70 cases was divided into two<sup>8</sup> groups: 1) acquitted (36) and 2) convicted doctors (34). Overall, the conviction rate for medical error was 49%, compared to 51% for acquittal. In Group 1, acquittal occurred in 39% of cases due to properly applied ICF, and in 61% due to other causes. In Group 2, the absence of the document represented 50% of the grounds for conviction mentioned.

Historically, the first reported case-law decision concerning the ICF was the *Schloendorff v. Society of New York Hospital* case, in the United States in 1914. According to Faden and Beauchamp, during the trial Judge Benjamin Cardozo stated that *every human being of adult years and sound mind has a right to determine what shall be done to his own body*<sup>10</sup>. This stands as a classic statement in the literature on the subject.

Brazilian scholars have not reached a consensus on the translation of the English expression “informed consent,” varying between the following terms: “*consentimento pós-informação*,” “*consentimento consciente*” and “*consentimento informado*,” the most commonly used. The

physician’s liability to warn the patient before the procedures became relevant in Brazil in 1990 with the CPC, which, as already pointed out, defines these professionals as service providers. However, unlike other professionals, their liability depends on the judgment of negligence<sup>1</sup>.

The concept of “consumption” related to health services has increased the number of lawsuits against physicians, but in many cases the interpretation of “medical error” is incorrect, and the occurrence of damage is sufficient to configure medical liability without negligence being clearly defined. However, failure to comply with the duty to warn is expressive and constitutes professional error, contributing to their conviction.

The doctor is responsible for subjective civil liability, that is, the victim must prove that the damage occurred by faults (imprudence, negligence and malpractice) or willful misconduct of the agent. The slightest misconduct forces the agent to compensate the victim, even when there was no intent<sup>11</sup>. In certain cases, proof of guilt is not required and its presumption is sufficient, with the inversion of the burden of proof. It is then up to the defendant to prove the absence of all guilt for the damage.

There are certain requirements to determine the liability of the doctor according to article 186 of the Civil Code: 1) culpable conduct of the agent, clear in the expression “one who, by voluntary action or omission, negligence or imprudence”; 2) causal link, expressed in the verb “to cause”; 3) damage, revealed in the expressions “violate rights” and “cause harm to others”<sup>5</sup>. Therefore, verifying the damage is not enough to confirm the doctor’s civil liability and the consequent conviction – it is necessary to investigate the assumptions of the decided norm.

The ICF must comply with certain rules to be legally validated. As with any contract, the capacity to exercise civil rights is essential, and therefore the text should be clear for the best understanding of the average citizen, with letters in readable size and individualized content. The document also needs to be signed voluntarily, without any coercion, by patients or their legal representatives. They should also participate in the preparation of the document – always having their autonomy respected – provided that this does not interfere with the good professional practice. Otherwise, the physician alone will bear the entire burden of the intervention<sup>12</sup>.

As already pointed out, the ICF is a one-sided legal act that does not provide such right to the doctor; that is, its effects are limited to the manifestation of the patient's will<sup>13</sup>. Although essentially produced to ensure consumer rights, the ICF has been seen by Law as an important defense strategy for physicians when properly applied, setting up a fair, balanced, safe and reliable relationship, translating the fulfillment of the professional duty to warn.

## Aesthetic procedures

Aesthetic procedures are peculiar compared to those of therapeutic nature. In this case patients are completely healthy, but seeks the doctor to improve their appearance and self-esteem, hoping that such investment will bring them psychological comfort<sup>14</sup>. The doctor needs to be sensitive when caring for this type of patient, and after screening they are also responsible for warning the patient of all procedural details. As such, the duty to warn becomes much more judicious than for other medical interventions.

Currently, dissatisfaction with the results of aesthetic procedures is widely reported. This denotes the subjective perception of the patient regarding their expectations and demonstrates misconceptions in the interpretation of the CPC, as the doctor cannot answer for the personal discontent of others, nor for the psychological traumas of a lifetime.

Given the praise of the ICF by courts in general, especially concerning aesthetic procedures, we observed a need to evaluate the real legal effectiveness of this document for the defense. The impact of this form on court decisions can be assessed by analyzing previous sentences for surgical and non-surgical aesthetic procedures. In the cases evaluated in this study, we found almost equal incidence of acquittal (51%) and conviction (49%) of doctors, and technical errors (faults) were distinguished from the duty to

warn to better evaluate the scope. The acquittal of the professional for the proper application of the ICF was significant (39%) compared to other causes that prompted the court to decide on behalf of the doctor. However, 50% of convictions were motivated by the absence of the form, indicating the importance of this document for the defense of physicians.

However, many problems arising from situations that are independent from medical action (inherent to the procedure and to any individual) are often considered medical errors by patients. Similarly, the lack of a ICF is seen by courts as professional negligence, even if there is no technical error.

The results obtained in this study allow to state that many judges consider the absence of ICF a sufficient reason to condemn the professional, understanding that this denotes lack of ethics and good faith of physicians in fulfilling their duty to warn the patient and respect the principles of autonomy and human dignity. The patient has the right to know all the details of the procedure and to choose to perform it or not.

## Final considerations

In this research, despite the almost equal number of acquittals and convictions, the proper application of the ICF had major impact on the exculpation of doctors. The greatest influence on the condemnation was the lack of this document, directly confronting the legal principles of autonomy and human dignity. From this we can conclude that the ICF competes with the pillars of civil liability already well established in law. Such document fulfills an essential role in the medical routine, especially for aesthetic procedures, when patients are completely healthy and seeks only to improve their physical appearance. The ICF constitutes indisputable evidence to be used by the physician in their defense.

## References

1. Brasil. Lei nº 8.078, de 11 de setembro de 1990. Dispõe sobre a proteção do consumidor e dá outras providências. Diário Oficial da União [Internet]. Brasília, 12 set 1990 [acesso 21 jan 2020]. Disponível: <https://bit.ly/3gk7BFO>
2. Brasil. Constituição da República Federativa do Brasil 1988. Brasília: Senado Federal; 1988.
3. Conselho Federal de Medicina. Resolução CFM nº 2.217, de 27 de setembro de 2018. Aprova o Código de Ética Médica. Diário Oficial da União [Internet]. Brasília, 1º nov 2018 [acesso 21 jan 2020]. Disponível: <https://bit.ly/3jXfAKQ>

4. Conselho Federal de Medicina. Resolução CFM nº 1.246, de 8 de janeiro de 1988. Código de Ética Médica. Diário Oficial da União [Internet]. Brasília, 26 jan 1988 [acesso 6 ago 2020]. Disponível: <https://bit.ly/3almfug>
5. Brasil. Lei nº 10.406, de 10 de janeiro de 2002. Institui o Código Civil. Diário Oficial da União [Internet]. Brasília, 11 jan 2002 [acesso 21 jan 2020]. Disponível: <https://bit.ly/33dReXi>
6. Marques CL. A responsabilidade dos médicos e do hospital por falha no dever de informar ao consumidor. Rev Trib. 2004; 93(827):11-48.
7. Conselho Nacional de Saúde. Resolução CNS 196/1996. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Bioética [Internet]. Porto Alegre: UFRGS; [s.d.] [acesso 21 jan 2020]. Disponível: <https://bit.ly/3fcX8uc>
8. Manzini MC. Valor jurídico do termo de consentimento informado em procedimentos estéticos [dissertação]. Santo André: Faculdade de Medicina do ABC; 2018.
9. Links Tribunais. ConJur [Internet]. [s.d.] [acesso 21 jan 2020]. Disponível: <https://bit.ly/2DiWCOc>
10. Faden RR, Beauchamp TL. A history and theory of informed consent. Nova York: Oxford University Press; 1986. p. 392.
11. Melo ND. Responsabilidade civil por erro médico: doutrina e jurisprudência. 2ª ed. São Paulo: Atlas; 2013.
12. Stancioli BS. Relação jurídica médico-paciente. Belo Horizonte: Del Rey; 2004.
13. Roberto LMP. Responsabilidade civil do profissional da saúde e consentimento informado. Curitiba: Juruá; 2006.
14. Magalhães TAL. O dano estético: responsabilidade civil. 2ª ed. São Paulo: Editora Revista dos Tribunais; 1999.


#### Participation of authors

Merlei Cristina Manzini conducted the bibliographic research and wrote the manuscript. Carlos D'Apparecida Santos Machado Filho and Paulo Ricardo Criado coordinated the study and reviewed the article.


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