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Informed Consent Form and the Right to Information in Legal Relationships Between Doctor and Patient.

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Abstract IT: Questo studio si propone di indagare, utilizzando il metodo della ricerca bibliografica e l'analisi dottrinale e giurisprudenziale, come il Modulo di Consenso Informato possa essere considerato un'espressione del diritto all'informazione garantito ai consumatori nella relazione giuridica tra medico e paziente. A tal fine, verrà inizialmente dimostrata la rilevanza del diritto all'informazione nell'ambito del Codice di Protezione del Consumatore brasiliano, per poi caratterizzare la relazione medico-paziente come soggetta alle norme del Codice di Protezione del Consumatore, correlando la garanzia dell'informazione sancita dalla legge con la necessità che i pazienti siano informati sui loro trattamenti o procedure. Infine, verrà analizzata l'ipotesi proposta riguardante il Modulo di Consenso Informato.

Abstract EN: This study aims to investigate, using the bibliographic research method and doctrinal and jurisprudential analysis, how the Informed Consent Form can be considered an expression of the right to information guaranteed to consumers in the legal relationship between doctor and patient. To this end, it will initially demonstrate the relevance of the right to information within the scope of the Brazilian Consumer Protection Code, and then characterize the doctor-patient relationship as one subject to the norms of the Consumer Protection Code, correlating the guarantee of information enshrined by the law with the need for patients to be informed about their treatments or procedures. Finally, the proposed hypothesis concerning the Informed Consent Form will be analyzed.

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Sommario: 1. Introduction. – 2. The Right to Information in the Consumer Protection Code. – 3. The Doctor-Patient Relationship as a Consumer Relationship. – 4. The Patient's Right to Information. – 5. The Informed Consent Form as an Expression of the Right to Information. – 6. Final Considerations.

1. Introduction.

The doctor-patient relationship has been evolving for centuries. Since antiquity, medicine was initially practiced in connection with religious cults, and it is now highly developed technologically and entirely tied to the field of science. Over the course of this relationship's evolution, the doctor has ceased to be seen as an authority wielding the power to save lives and has come to be recognized as a supplier in a consumer relationship.

The right to information, in turn, is one of the fundamental pillars of consumer relationships, ensuring consumers access to clear, precise, and adequate information about products and services. In the context of the doctor-patient relationship, the issue of information takes on even greater relevance, as it concerns health, self-determination, and the well-being of individuals. This leads to the discussion about whether the Informed Consent Form can be considered an expression of the right to information in consumer relationships between doctor and patient.

This article aims to analyze, in doctrine and jurisprudence, the relationship between doctors and patients, to establish it as a consumer relationship and, based on this conclusion, investigate whether the Informed Consent Form can be considered an expression of the right to information guaranteed by Article 6(III) of the brazilian Consumer Protection Code.

The topic is important and timely as it seeks to harmonize the legal and ethical norms that, based on the right to information, must regulate the legal relationships between medical professionals and their patients.

2. The Right to Information in the Consumer Protection Code.

The Brazilian Consumer Protection Code provides in its Article 6(III) that the right to clear and adequate information is one of the basic rights of consumers. In addition to the provisions in the Consumer Protection Code, the right to information is also enshrined in the brazilian Constitution, being explicitly listed among the fundamental rights in Article 5(XIV), which states that *"access to*

information is assured to all, and confidentiality of the source is protected when necessary for professional practice"[1].

In the Brazilian legal framework - and, by extension, in consumer relations - information has a dual aspect: the consumer's right to be informed and the supplier's duty to provide information. Minister Humberto Martins explains this duality as follows: *"When consumers receive information about a product or service, they will decide whether or not to purchase it. If the information is complete, clear, and efficient, the consumer will make an informed choice, but if the information is partial, ambiguous, or false, the consumer's right to make an informed choice is violated. Since the consumer has the right to information, the supplier, in turn, has the duty to inform, which is essential for operating in the market and respecting the consumer's basic right to be informed*"[2][3].

Thus, information emerges as a key factor in consumer choices, and it must be provided clearly even at the pre-contractual stage. The importance of respecting this right, and of fulfilling the corresponding duty, lies in the presumption of consumer vulnerability. Therefore, suppliers, who hold all the knowledge about their product or service, must present it fully to potential consumers.

There is an intrinsic connection between the right to information and good faith in contractual relations, as well as with the duty of loyalty, as demonstrated by Minister Nancy Andrighi: *"Beyond being a basic right of consumers, proper information disclosure is also a reflection of the loyalty inherent to good faith and is the foundation from which it is possible to determine the alignment between the offered service and what is actually provided"*[4].

Judith Martins Costa teaches that the duty to inform is embedded within the duty of loyalty and is often confused with veracity. However, it goes beyond mere truthfulness, as it means *"contributing positively to the interests of others, and, in the case of society, to the common interest"*[5].

Paulo Luiz Netto Lôbo clarifies that the duty to inform in consumer relations must meet three criteria: adequacy, sufficiency, and veracity: *"Adequacy pertains to the methods and content of the information. The means of communication must be compatible with the product or service in question and with the typical consumer. The signs used (images, words, sounds) must be clear and precise to encourage understanding. (…). Sufficiency relates to the completeness and thoroughness of the information. Prior to the advent of consumer law, it was common for information to be omitted, incomplete, or intentionally misleading, especially concerning unfavorable data about a product or service. For example, the lack of information about the expiration date of a food product creates the false impression that it can still be*

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[1] Brasil, *Constituição da República Federativa do Brasil*, Brasília, 1988.

[2] H. MARTINS, *O Dever de Informar e o Direito à Informação*, 2020, available at the following link https://www.conjur.com.br/2020-fev-19/dever-informar-direito-informacao-parte.

[3] All quotations from Brazilian authorities in this article have been translated from Portuguese to English by the author, who assumes full responsibility for the translated content.

[4] Brasil, Superior Tribunal de Justiça, Recurso Especial 988595 SP 2007/0217038-3, Relatora: Ministra Nancy Andrighi, Julgamento: 19/11/2009, Publicação: DJe 09/12/2010.

[5] J. M. COSTA, *A Boa-Fé no Direito Privado: Critérios para a sua Aplicação*, São Paulo, 2018, 594.

consumed, whereas sufficient information would allow the consumer to choose the most recently manufactured product. A widely reported example is the tobacco industry's concealment of information regarding the health risks of smoking. (…). Veracity is the third major requirement of the duty to inform. Information is considered truthful when it accurately reflects the characteristics of the product or service, including correct details about composition, content, price, warranties, and risks. Partially truthful or false advertising is considered deceptive, and consumer law pays special attention to its consequences"[6].

Thus, adequacy relates to the manner in which the information is conveyed and must align with the product or service offered. Sufficiency, on the other hand, pertains to the quantity and quality of the information, which cannot be withheld from the consumer. Lastly, veracity, as expected, concerns the degree of fidelity between the information provided to the consumer and reality.

By combining the three requirements presented by Netto Lôbo with Judith Martins Costa's teaching that information goes beyond mere veracity, it is evident that the right to information is extremely broad and of great importance to the consumer.

In this light, the Consumer Protection Code emphasizes the importance of enforcing this basic right, not only in Article 6(III) but also in Articles 4(IV), 8, 9, 12, 14, 18, 19, 20, 30, 31, 36, 37, 39(VII), 43, 46, 52, 54(§3), 72, and 73.

Information, therefore, can be affirmed as one of the foundational elements of Consumer Law and, not by chance, it is listed as one of the principles of the brazilian National Policy on Consumer Relations[7]. Following this idea, Minister Herman Benjamin states: "One of the basic rights of consumers—perhaps the most fundamental of all, hence its express provision in Article 5(XIV) of the 1988 Constitution—is the right to adequate and clear information about different products and services, with correct specification of quantity, characteristics, composition, quality, and price (Article 6(III) of the CDC). It is, without exaggeration, one of the cornerstones of the microsystem and modern society, which also includes protection against misleading and abusive advertising" (CDC, Articles 6(IV) and 37)[8] .

The importance of the right to information is such that its violation - either by providing insufficient or inadequate information - leads to liability without the need to prove fault on the part of all involved in the supply chain[9]. Similarly,

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[6] P. L. N. LÔBO, *A Informação como Direito Fundamental do Consumidor*, in C. L. MARQUES, B. MIRAGEM (ed.), *Direito do Consumidor, proteção da confiança e práticas comerciais*, São Paulo, 2011.

[7] Article 4, IV of the Consumer Protection Code.

[8] Brasil Superior Tribunal de Justiça. AgRg no AgRg no REsp 1.261.824/SP. Relator Ministro Herman Benjamin. Data de Julgamento: 14.02.2012, Segunda Turma. Data de Publicação: DJe 09.05.2013.

[9] *"Article 12: The manufacturer, producer, builder, whether domestic or foreign, and the importer are liable, regardless of fault, for compensating damages caused to consumers by defects resulting from design, manufacture, construction, assembly, formulas, handling, presentation, or packaging of their products, as well as for insufficient*

information that fails to meet the criterion of truthfulness is classified as misleading advertising under Article 37(§§1 and 2) of the CDC.
With the relevance of the right/duty of information in consumer relations established, we now move to the characterization of the doctor-patient relationship as a consumer relationship, and subsequently examine how the right to information is handled in this context.

3. The Doctor-Patient Relationship as a Consumer Relationship.
For centuries, the role of the doctor was shrouded in religious and mystical aura, with health and death attributed to divine will.[10] In this context, there was no concept of medical responsibility, much less a consumer relationship between the doctor and the patient, as the doctor was not even considered a professional but rather a divine agent involved in a religious practice. It was Hippocrates who changed this scenario. Known to this day as the "Father of Medicine" the Greek philosopher and physician abandoned the traditions that viewed medicine as a religious technique and brought the profession closer to biological and natural sciences[11]. The updated Hippocratic Oath[12] is still recited by all doctors at their graduations.
More recently, in the early 20th century, the doctor became a paternalistic figure, and it was common to have a family doctor, who was called upon in all moments of need. With this perception of the medical professional, a stereotype was created—which can still be observed today—that the doctor is a hero, an authority figure with the power to save lives and, therefore, a specialist who *"generated the reciprocal respect, recognition, and reverence from society*"[13]. At that time, the doctor-patient relationship was based on trust.
Today, however, this bond has changed. The doctor is no longer the trusted family confidant but rather a service provider, as explained by Maria de Fátima Freire de Sá and Bruno Torquato de Oliveira Naves: *"While we may come into contact with doctors who offer us their friendship, affection, and consideration, the fantastic scientific development, the emergence of large hospitals and health centers, and the increasing need to be tied to a health plan have distanced the medical professional from their patient. (...) The current perspective is of a consumerist society, increasingly aware of its rights and more demanding regarding results. The growing specialization of doctors, although necessary, has logically distanced them from the patient. The doctor is no longer the family's trusted*

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or inadequate information about their use and risks." And "Article 14: The service provider is liable, regardless of fault, for compensating damages caused to consumers by defects related to the provision of services, as well as for insufficient or inadequate information about their use and risks."
[10] R. R. AGUIAR JÚNIOR, *Responsabilidade Civil do Médico*, in S. F. Teixeira (coord.), *Direito & Medicina*, Belo Horizonte, 2000, 135.
[11] G. BERGSTEIN, *A Informação na Relação Médico-Paciente*, São Paulo, 2013.
[12] CRM-PR, *Juramento de Hipócrates*, available at the following link https://www.crmpr.org.br/Juramento-de-Hipocrates-1-53.shtml.
[13] T. V. BOMTEMPO, *A Informação: Direito Fundamental do Consumidor na Relação Médico-Paciente*, in *Revista Síntese: Direito Civil e Processual Civil*, 12, 83, 2013, 9-33.

professional but a "specialist" recommended by someone or coincidentally found during a hospital visit, or the one covered by the patient's health plan"[14].

This conception, however, has sparked intense doctrinal debate and still faces some resistance. In the brazilian context, the Consumer Protection Code defines a supplier as: *"Art. 3: A supplier is any natural or legal person, public or private, domestic or foreign, as well as unincorporated entities, engaged in the activity of producing, assembling, creating, constructing, transforming, importing, exporting, distributing, or commercializing products or providing services*"[15].

The consumer, in turn, is defined as "any natural or legal person who acquires or uses a product or service as the final recipient."[16] Thus, it is evident that the doctor, as a service provider in the field of health, fits within the definition of a supplier, and the patient, as the one who uses the service as the final recipient, qualifies as a consumer. With the supplier (doctor), the consumer (patient), and the service (healthcare) in place, it is logical to classify this relationship as a consumer relationship.

The Consumer Protection Code even explicitly mentions liberal professionals, such as doctors and other health professionals, stating in Article 14(§4) that their personal liability will be assessed based on fault.

Conversely, the Medical Ethics Code, in its Chapter I, Article XX, states that *"the personal nature of the physician's professional performance does not characterize a consumer relationship*"[17].

However, the Federal Council of Medicine, being a federal autarchy, does not have the power to legislate. Therefore, despite the provision in the Medical Ethics Code, Brazilian doctrine and jurisprudence have affirmed that the doctor-patient relationship does constitute a consumer relationship.

As early as 2004, Claudia Lima Marques asserted: *"Today, there is no longer any doubt in our country about the application of the Consumer Protection Code to the services provided by doctors, hospitals, and private clinics, whether in individual or group medicine through health insurance or health plans*[18].

This remains the position of the doctrinal expert, who in a recent publication[19] questioned whether the consumer's primary concern in doctor-patient relationships would be (i) a duty of service: performing the treatment; (ii) an ancillary duty: informing the risks of the treatment and allowing the patient to

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[14] M. F. F. de SÁ, B. T. de O. NAVES, *Manual de Biodireito*, 3 ed., Belo Horizonte, 2015, 79-80.
[15] Brasil, Lei nº 8.078, de 11 de setembro de 1990, *Código de Defesa do Consumidor*.
[16] Article 2, *caput*.
[17] Conselho Federal de Medicina, Recomendação CFM nº 1, de 21 de janeiro de 2016, Brasília.
[18] C. L. MARQUES, *A Responsabilidade dos Médicos e do Hospital por Falha no Dever de Informar ao Consumidor*, in *Revista dos Tribunais*, 827, 2004, 11-48.
[19] C. L. MARQUES, *Direito do Consumidor - 30 anos de CDC*, São Paulo, 2020, 27.

make their choice; (iii) a collateral duty: properly performing the treatment using the most appropriate techniques; or (iv) a combination of all these duties.
The courts have also adopted the stance that the doctor-patient relationship constitutes a consumer relationship and must be governed by the Consumer Protection Code. The Superior Court of Justice has based its decisions on this principle, as illustrated by the following case:
Civil procedural law. Internal appeal in a special appeal. Civili liability. Medical error. Impossibility of third-party claims. Art. 88 of the cdc. Stj summa n. 83. Non-occurance of arts. 489 and 1.022 of the 2015 c.p.c. decision upheld.
1. According to the Superior Court of Justice's jurisprudence, the Consumer Protection Code applies to medical services, including the impossibility of third-party claims, as provided in Article 88 of the CDC. The STJ Summa n. 83 applies[20].
Thus, despite opposing opinions[21], he doctor-patient relationship should indeed be considered a consumer relationship and, consequently, treated according to the guidelines of the Consumer Protection Code. This approach is even recommended in consumer law[22] and medical law manuals[23].
Once the doctor-patient relationship is characterized as a consumer legal relationship, we proceed to analyze the right to information in these relationships.

4. The Patient's Right to Information.
As demonstrated in the previous chapter, the doctor-patient relationship evolved from a paternalistic model to a service provision relationship. One of the factors that motivated this evolution was the growing movement toward humanizing medicine, which no longer treats patients merely as recipients of care but as consumers of medical services. In this regard, Roxana Borges notes: *"In the medical field, efforts have been made to humanize medicine further. One reflection of this effort is the consideration of the patient as a client. The change in terminology is significant. By treating the sick person as a client rather than a patient, they are elevated to the status of a subject, no longer merely someone who passively waits, as the term 'patient' suggests. (...) The client—no longer the patient—decides whether they want the treatment offered by the doctor, and throughout the course of the treatment, they can also decide whether to continue with it"*[24].

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[20] Brasil Superior Tribunal de Justiça. AgInt no AREsp 1630070 SP 2019/0357882-3. Relator: Ministro Antonio Carlos Ferreira. Data de Julgamento: 07/06/2021, Quarta Turma. Data de Publicação: DJe 14/06/2021.
[21] Notably, prominent names in Medical Law, such as Miguel Kfouri, argue against the applicability of the Consumer Protection Code (CDC) in doctor-patient relationships.
[22] J. G. B. FILOMENO, *Direitos do Consumidor*, 15 ed., São Paulo, 2018, 19.
[23] A. V. A. P. SOUZA, *Direito Médico*, São Paulo, 2022, 38.
[24] R. C. B. BORGES, *Direito de Morrer Dignamente: Eutanásia, Ortotanásia, Consentimento Informado, Testamento Vital, Análise Constitucional e Penal e Direito Comparado*, in M. C. C. L. SANTOS (ed.), *Biodireito: ciência da vida, os novos desafios*, São Paulo, 2001.

Another important factor in this evolution is the advent of the internet and, in particular, search engines. Access to information has empowered patients, who are no longer passive subjects in their treatment and now have the theoretical knowledge to question their doctors, as Gilberto Bergstein explains: *"In recent decades, from a sociological perspective, a paradigm shift in the doctor-patient relationship has occurred. This is mainly due to the increase in the dissemination of technical information (especially medical information), particularly through the internet. Until a few decades ago, the prevailing model was paternalistic, where the doctor was considered virtually omnipotent—"the holder of truth," a "quasi-deity."* This model evolved into a relationship in which the patient questions the doctor's actions, demanding explanations about the illness, the treatment alternatives to be adopted, and the consequences that may arise[25]. It is not just the patients who are seeking information; doctors are also being encouraged to share information with their clients about diagnoses, the treatments being applied, and the potential consequences. This behavior is a result of the humanization of medicine and is undoubtedly linked to treating patients with dignity. Still, it also arises as a means for healthcare professionals to avoid legal liability in the face of the increasing trend of healthcare litigation[26]. Therefore, information becomes a guiding principle in doctor-patient relationships, as evidenced in Brazil by the Medical Ethics Code, which explicitly mentions the duty to inform on two occasions. The first mention is in Title II, which deals with professional responsibility, where Article 13 prohibits doctors from *"failing to clarify the patient about the social, environmental, or professional determinants of their illness*"[27].

This article reflects the Federal Council of Medicine's concern that doctors inform their patients of circumstances beyond the diagnosis that may affect their health. Regarding the diagnosis itself, Article 34 states that it is prohibited for doctors to *"fail to inform the patient of the diagnosis, prognosis, risks, and objectives of the treatment, except when direct communication may cause harm, in which case the communication must be made to the patient's legal representative."*[28].

It is important to emphasize that there is an exception to the obligation to inform the patient. It does not mean denying the right to information but rather passing it on to a third party—the legal representative—when it is determined that communication may harm the patient. It should be noted that this is the only instance accepted by the Medical Ethics Code in which doctors may refrain

[25] G. BERGSTEIN, *A Informação na Relação Médico-Paciente*, São Paulo, 2013, 109.

[26] For more information on the high number of claims against doctors in Brazil, see: M. KFOURI NETO, *A Responsabilidade Civil do Médico*, in *Revista dos Tribunais*, 654, 1990, 57-76.

[27] Conselho Federal de Medicina, Resolução CFM nº 2.217, de 27 de setembro de 2018, Brasília.

[28] *ibid.*

from informing their patients about the diagnosis. Therefore, what some doctors call a "benevolent lie" is unacceptable.

Thus, it is clear that the medical community recognizes the existence of the patient's right to information. This right is legally protected by Article 6, III of the Consumer Protection Code and by the Constitution, as explained in the second chapter of this article.

However, it is not enough to simply inform. The information must be provided by the doctor in a clear and comprehensive manner, enabling the patient to fully understand the situation and providing them with sufficient resources to make informed decisions about their treatment.[29] In this regard, it is relevant to mention Helio Antonio Magno's example concerning the distinction between information and clarification: *"If the doctor tells the patient: "You need to undergo a CT scan with contrast. Do you agree?" The patient will likely automatically say yes. This is because they were merely informed about the test. However, if the doctor 'explains' to the patient what a CT scan is, what contrast is, and the adverse effects it may cause, the patient will likely want to discuss the possibility of alternative tests or even not undergo any tests. This is the major difference between 'informing' and 'clarifying'*"[30].

It is therefore the doctor's responsibility not only to describe the treatment or procedure to the patient but to explain its operation, the pros and cons of its execution, and any potential complications, considering the patient's clinical condition. Only in this way can the patient be said to be fully aware of their situation and able to make an informed decision about undergoing a treatment or procedure.

Only when clarification is provided will the patient's right to information be fulfilled, as Sérgio Cavalieri Filho explains: *"The content of the doctor's duty to inform, according to unanimous doctrine, includes all necessary and sufficient information to fully explain the patient's relevant aspects for deciding whether to undergo the procedure, such as risks, treatment outcomes, success rates, side effects, and other important factors*"[31].

It is in light of this context that the concept of informed consent is established in the doctor-patient relationship.[32] This consent results from the process of qualified and therefore clarified information from the doctor, allowing the patient to consent to the treatment or procedure.

This consent from the patient is rooted in their self-determination, which can only be actualized in a context of knowledge, as Maria Helena Diniz explains: *"An expression of the patient's autonomy principle is informed consent, a voluntary decision-making act based on clear, simple, precise, honest, and intelligible medical information about the diagnosis (with clarification about the illness and its progression), prognosis, side effects of*

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[29] L. DADALTO, *Testamento Vital*, 6 ed., São Paulo, 2022, 2.

[30] H. A. MAGNO, *A Responsabilidade Civil do Médico diante da Autonomia do Paciente*, in A. M. G. e Silva (coord.), *Biodireito e bioética: uma introdução crítica*, Rio de Janeiro, 2005, 327.

[31] S. C. FILHO, *Programa de Responsabilidade Civil*, São Paulo, 2023.

[32] It is important to highlight that the term "informed consent" is not exclusive to doctor-patient relationships, as it is also adopted in other fields.

treatment, the most appropriate therapy, specifying its goals, duration, consequences, and benefits, the doctor's plan for post-treatment care, any necessary special care, expected discharge date, consequences of refusing treatment, surgery to be performed, potential risks, alternatives to medical practices, and the expected advantages or disadvantages of an action (...)"[33].

Claudia Lima Marques shares this view, emphasizing the close connection between informed consent and the consumer's right to information: *"In other words, without clear and sufficient information, proper clarification, and warnings about the risks of future medical interventions, there is no free and rational consent from the consumer in Brazil. There is a violation of their autonomy, a breach of good faith, and noncompliance with a basic duty of doctors and a fundamental right of consumers: access to information!"*[34].

However, in Brazil, there is a noticeable trend among medical clinics and hospitals to reduce the process of clarification through information to a written document called the Informed Consent Form (ICF). The next chapter will examine this document and its validity as an expression of the right to information.

5. The Informed Consent Form as an Expression of the Right to Information.

In recent years, it has become common practice in Brazil to require patients to sign an informed consent form before undergoing exams and surgical procedures. These documents typically specify the purpose of the intervention and its potential consequences. The idea is that the ICF[35] serves as documentary proof that the doctor's duty to inform has been fulfilled.

In 2016, the Federal Council of Medicine issued Recommendation 1/2016, which provides guidelines for obtaining informed consent. The directive emphasizes that, although it may be materialized in a written document, informed consent is not an agreement but rather a process of dialogue between the doctor and the patient[36]. The recommendation advises doctors to set aside time to answer the patient's questions: *"Informed consent should only be given by the patient when they are convinced that the necessary clarifications have been provided regarding the procedure, its risks, benefits, and consequences. In addition to understanding the information, the patient must accept it as truthful and not manipulated. To achieve this, time must be set aside for the patient to ask questions and accept the information. For example, particularly in cases of negative prognoses, the patient may initially experience a denial phase*

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[33] M. H. DINIZ, *O Estado Atual do Biodireito*, São Paulo, 2017.

[34] C. L. MARQUES, *A Responsabilidade dos Médicos e do Hospital por Falha no Dever de Informar ao Consumidor*, in *Revista dos Tribunais*, 827, 2004, 11-48.

[35] The acronym that legal doctrine and the medical community have been using to refer to the Informed Consent Form.

[36] Conselho Federal de Medicina, Recomendação CFM nº 1, de 21 de janeiro de 2016, Brasília.

after learning about their situation, making it necessary, whenever possible, to allow time for adaptation"[37].

This recommendation aligns with the perspective of bioethics, as explained by Gustavo Borges and Roberta Weirich Mottin: *"According to bioethics, informed consent is a process, not merely the signing of a form. This process results from the trust established between the doctor and the patient, and it may or may not be accompanied by a document called an "informed consent form." A well-documented medical record that includes the patient's entire history and details of the procedures performed will also serve as evidence in a potential legal defense*"[38].

The recommendation continues, explaining that written consent is not always necessary, but if written, the patient should read the document outside the doctor's office, discuss it with their family, and only then sign and return it to the doctor. The written informed consent, recommended by the directive and referred to as the ICF, must be written in Portuguese and must include the following:

"a) Justification, objectives, and a succinct, clear, and objective description of the procedure in accessible language for the patient;

b) Duration and description of potential discomforts during the procedure;

c) Expected benefits, risks, alternative methods, and consequences of not performing the procedure;

d) Post-procedure care the patient should take;

e) Declaration by the patient that they have been properly informed and clarified about the procedure, with their signature;

f) Declaration that the patient is free to refuse the procedure without penalty or prejudice to their care;

g) Declaration by the doctor that they have clearly explained the entire procedure;

h) Full names of the patient and doctor, as well as the contact information of any relevant team members, so that they can be easily reached by the patient;

i) Signature or fingerprint identification of the patient or their legal representative, and the doctor's signature;

j) Two copies, one for the patient and one to be kept in the medical records"[39].

It is important to note again that the Federal Council of Medicine does not have legislative power, and this document is only a recommendation, not an administrative requirement.

Despite the Council's 2016 initiative, experience shows that in many cases, patients are not fully informed, and a generic document is handed to them instead. Regarding such generic forms, Antônio Carlos Efing emphasizes: *"(...) it is necessary for information not to be a mere legal formality but to genuinely clarify the*

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[37] *ibid.*

[38] G. BORGES, R. W. MOTTIN, *Responsabilidade Civil por Ausência de Consentimento Informado no Atendimento Médico: Panorama Jurisprudencial do STJ*, in *Revista dos Tribunais*, 64, 2015, 119-143.

[39] Conselho Federal de Medicina, Recomendação CFM nº 1, de 21 de janeiro de 2016, Brasília.

consumer's doubts, thus preventing contractual frustration and meeting their legitimate expectations"[40].

These generic forms, which are mere legal formalities, are referred to in doctrine as "blanket consent,"[41] and a recent ruling by the Superior Court of Justice (STJ) held that these are not valid as informed consent:

Special Appel. Action for moral madame. Surgical procedure performer to trat obstructive sleep apnea syndorm (Osas). Patient's death. Failure to provide jurisdictional assistance. Non-occurence failure to inform about the surgery's risk. Only a generic consent (blande consent) was prodived, which is insufficient to guarantee the fundamental right of the patient's self-determination. The court upholds the reinstatement of damages award. Partial appeal grated[42].

In this STJ case, the family of a patient who died during elective surgery sought compensation for moral damages from the surgeon and anesthesiologist, alleging that the doctors had failed to inform the patient about the risks of the surgery. It was proven in court that the doctors never informed the patient that his physical condition (obesity and a base-of-tongue hypertrophy) could cause serious complications during the surgery, which ultimately led to his death.

In his decision, the presiding Minister Marco Aurélio Bellizze stated that patients have the right to know the risks of the procedures they will undergo, as guaranteed by Articles 6(III) and 14 of the Consumer Protection Code, Article 15 of the Civil Code, and Article 22 of the Medical Ethics Code. The Minister concluded that a simple generic consent (blanket consent), agreeing to the surgery and its potential risks, does not constitute clear and precise information, thus violating the mentioned legal provisions and warranting compensation.

It is clear, therefore, that a signed form alone is not enough; there must also be an explanation from the doctor about the treatment or procedure. It is not suggested here that all TCLE forms are invalid or without legal effect. In many cases—and this is what should be expected—the signing of the form occurs only as a formalization of an explanation process, and in such cases, the document is fully valid.

The Superior Court of Justice has even provided guidance for doctors to obtain written informed consent from patients: *"A doctor who obtains the patient's signature*

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[40] A. C. EFING, *Fundamentos do Direito das Relações de Consumo*, 5 ed., Curitiba, 2022, 140.

[41] North American doctrine has coined the use of the term for a broad and general consent, where the individual agrees to a wide range of activities or uses of their personal information without specifying each purpose individually.

[42] Brasil Superior Tribunal de Justiça. Recurso Especial 1848862 RN 2018/0268921-9. Relator Ministro Marco Aurélio Bellizze. Data de Julgamento: 05/04/2022 - Terceira Turma. Data de Publicação: DJe 08/04/2022.

on an informed consent form, thereby alerting them to potential post-operative issues, acts cautiously and in accordance with the principles of good faith"[43].

Thus, it is demonstrated that the Informed Consent Form can indeed serve as an expression of the consumer-patient's basic right to information, provided that the requirements for informed consent have been met. In such cases, the TCLE will only be valid as a guarantee of information if it reflects a process of dialogue between the doctor and the patient regarding the risks of the treatment or procedure.

6. Final Considerations.

This study sought to demonstrate the possibility that the Informed Consent Form can be considered an expression of the right to information enshrined in Article 6(III) of the brazilian Consumer Protection Code in the context of doctor-patient relationships.

To this end, we initially defined the concept of the right to information within Consumer Law, which was presented as a foundational guarantee of consumer relations, without which the consumer would not be able to make informed choices about products or services. As demonstrated, information must be provided clearly to the consumer from the pre-contractual stage, and just as it is a right of consumers, it is a duty of suppliers.

We then demonstrated that, despite doctrinal disagreements, the doctor-patient relationship constitutes a consumer relationship and must be governed by the Consumer Protection Code. At this point, we also presented the evolution of the doctor-patient scenario, which has shifted from a paternalistic relationship to a service provision model.

Considering the doctor-patient relationship as a service provision and categorizing it as a consumer relationship, we emphasized the importance of the duty of information between doctors and patients. We asserted that in such relationships, merely providing information is not enough; there must be sufficient clarification so that the patient can understand their situation and freely make a decision regarding the treatment or procedure to be undertaken.

Finally, we analyzed the validity of the Informed Consent Forms as expressions of the consumer-patient's right to information. We found that the document can be considered a valid expression of the right to information, provided it does not constitute a case of blanket consent, and the process of obtaining consent involves clear and detailed dialogue between the doctor and the patient regarding the risks of the treatment or procedure.

By following the appropriate legal guidelines for the use of the TCLE, medical professionals (especially doctors) and patients who are consumers of their

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[43] Brasil Superior Tribunal de Justiça. Recurso Especial 1.180.815/MG. Relatora Ministra Nancy Andrighi. Data de Julgamento: 19/08/2010 - Terceira Turma. Data de Publicação: DJe 26/8/2010.

services will likely reduce conflict and litigation, making it essential to adjust professional practices to comply with legal norms on this matter.

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