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# Informed consent form as evidence in the judiciary

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## Abstract

This article analyzes the term "free and informed consent" as evidence in the Judiciary. It analyzes Health Research Policy, socioeconomic factors, Federal Legislation, and the evolution of critical care, with the differences that exist between the countries researched. It demonstrates the accuracy or lack thereof of the term as evidence in the Judiciary, according to an analogy between the current legislations. A systematic review was carried out, including 15 articles in a qualitative synthesis, from Portuguese, French, Spanish, Italian, and English, published between 2002 and 2023. The results were made according to the understanding of their authors, according to the year and country. It was concluded that, when properly used, the term provides the professional, the institution, and the patient with autonomy and legal protection.

**Keywords:** Health research policy. Federal legislation. Socioeconomic factors. Evolution of critical care.

## Resumo

**Termo de consentimento livre e esclarecido como prova no Judiciário**

Este artigo analisa o termo de consentimento livre e esclarecido como prova no Judiciário. Analisam-se a política de pesquisa em saúde, fatores socioeconômicos, legislação federal, evolução nos cuidados críticos, com as diferenças existentes entre os países pesquisados. Demonstra-se a acuidade ou não do termo de consentimento como prova no Judiciário, conforme analogia entre as legislações vigentes. Realizou-se revisão sistemática de 15 artigos, em uma síntese qualitativa, em português, francês, espanhol, italiano e inglês, publicados entre 2002 e 2023. Os resultados foram classificados de acordo com o entendimento de seus autores, conforme o ano e país. Concluiu-se que, devidamente utilizado, o termo de consentimento fornece ao profissional, à instituição e ao paciente autonomia e proteção jurídica.

**Palavras-chave:** Política de pesquisa em saúde. Legislação federal. Fatores socioeconômicos. Evolução nos cuidados críticos.

## Resumen

**El consentimiento informado como prueba en el tribunal**

Este artículo analiza el término "consentimiento libre e informado" como prueba en el Poder Judicial. Analiza la política de investigación en salud, los factores socioeconómicos, la legislación federal y la evolución de los cuidados críticos, con las diferencias existentes entre los países investigados. Demuestra la precisión o falta de precisión del término como prueba en el Poder Judicial, según una analogía entre las legislaciones vigentes. Se realizó una revisión sistemática que incluyó 15 artículos en una síntesis cualitativa, en portugués, francés, español, italiano e inglés, publicados entre 2002 y 2023. Los resultados se elaboraron según la interpretación de sus autores, por año y país. Se concluyó que, cuando se utiliza correctamente, el término proporciona autonomía y protección legal al profesional, a la institución y al paciente.

**Palabras clave:** Política de investigación en salud. Legislación federal. Factores socioeconómicos. Evolución de los cuidados críticos.

Research

The authors declare no conflict of interest.

This article analyzes the signing of the informed consent form (ICF) by patients or their families, which allows physicians to perform medical procedures such as physical examinations and other diagnostic measures, medication administration, or follow-up care in critical cases. Informed consent involves the physician fully explaining their actions, a patient right recognized in Portuguese, Spanish, English, Italian and French, by law and case law [1,2].

Ethically, informed consent is a concept that ensures patients the ability to decide about their bodies, understanding the expected complications. In critical cases, however, it falls on their legal representatives to sign the ICF. Legally, it protects physicians against lawsuits. In Brazil, although there is no specific law on informed consent, its practice is situated and supported by various legal sources and ethical principles. The Brazilian Civil Code and Code of Ethics, along with specific laws and judicial decisions, reinforce the mandatory nature of informed consent and impose significant legal consequences for inadequacies [2,3].

A healthy adult has the right to decide what should be done with their body, and a physician cannot perform examinations or procedures against their will, even if for their benefit. All medical procedures require informed consent, and this information must be provided to the patient regardless of whether it is requested [3]. Regarding critical patients, the ICF must be signed by their legal representatives, as explained above.

According to the Federal Council of Medicine (CFM), as well as current laws and case laws in Brazil, withholding information is not permissible, except when the physician notes it may affect the patient's health interests. In that case, the physician may provide it to the family, with a nurse or other paramedic present as a witness. This information must be provided before the start of therapy, especially for high-risk medical procedures and critical care. Thus, any medical procedure with significant risks requires written consent signed by the patient or their legal representative after receiving information about the need for the procedure and its respective risks [3,4].

The completeness of informed consent is categorical for the provision of health services, as it is an agreement that promotes safety and comfort for physicians during their duties as healthcare providers [4-6]. In Brazil, numerous professionals use "defensive medicine" and reduce informed consent to a written document, the ICF, in an attempt to ensure patient safety regarding the information provided about the risks and benefits of a mandatory surgical procedure [1,3,5].

It is justified by the need to show that the ICF is required for proper medical practice aligned with legal precepts in Portuguese, French, Italian, Spanish and English, promoting changes in patient behavior, who becomes more participatory, interested in their diagnosis, in the procedures and treatment process, and in prompt recovery [2,4].

Contributing to a better understanding ofhealth policies, similar studies offer important perspectives for healthcare professionals in accordance with current legislation and case laws in the countries. The topic is important because informed consent guides physicians on ethical and legal obligations, contituting a primary mechanism for guaranteeing biotehical principles, health policies, justice and adequate patient care.

Thus, the present study has the general objective of showing the accuracy or lack thereof of the ICF in medical education and health policy as a means of proof in the Judiciary, as per the laws and cases laws of analyzed countries. Its specific objectives are to demonstrate its effects on the physician-patient relation as a means of proof in the Judiciary, and to describe in detail the process of informed consent, with the phases, risks, and benefits that contribute to the validity of obtaining it.

## Method

This section presents the primary survey of the database, according to the research protocol for identifying the studies used in the systematic review, allowing the researcher to map the increments and necessary information in their area of study, encompassing two procedures,

analysis and performance, evaluating the authors' activities and the scientific map used in simulating the research arrangement.

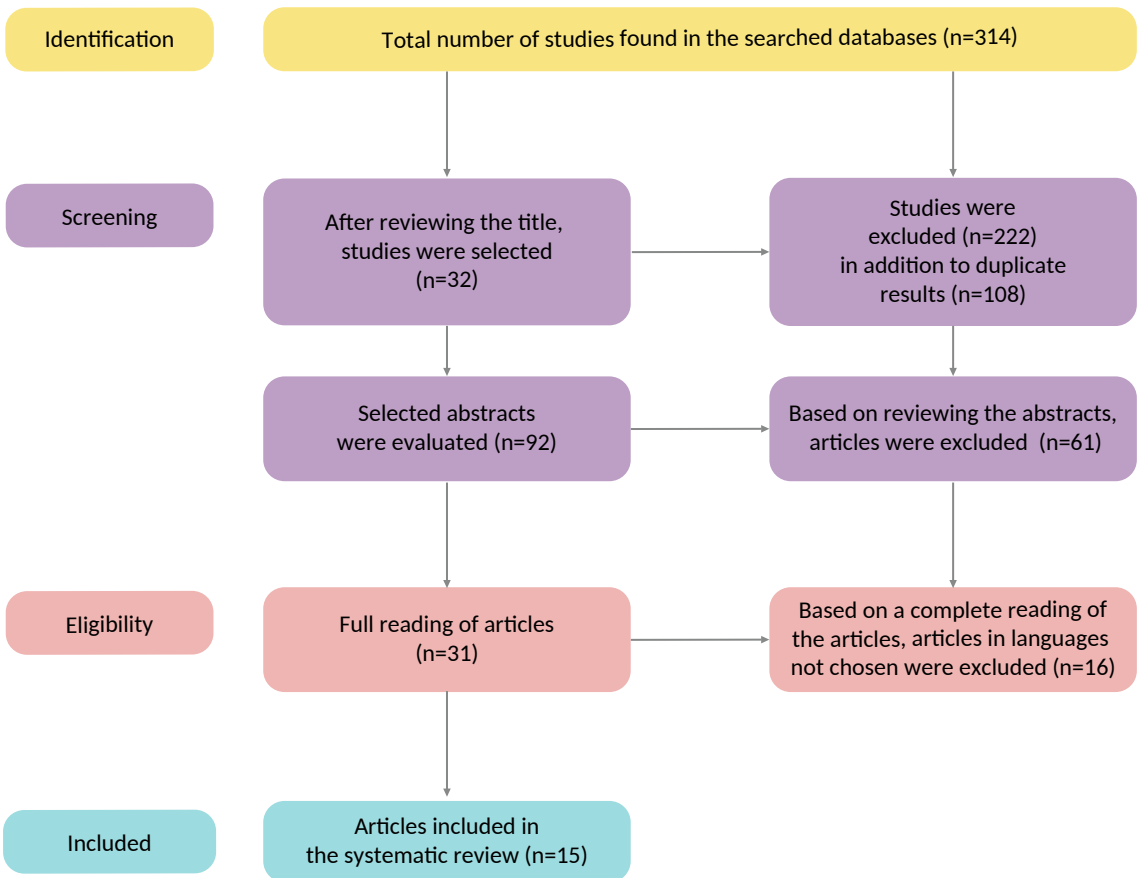
The questions used to conduct the study were:

1. What is the role of informed consent in protecting physicians considering health policies, socioeconomic factors, laws and case laws of each surveyed country?
2. Is informed consent considered a means of proof in in the Judiciary, including for critical care?

The search was conducted on the Coordination for the Improvement of Higher Education Personnel (CAPES) portal and Google Scholar, as such tools provide access to worldwide scientific production, including dissertations, papers published in events, and articles. The main databases available at CAPES are: ACM Digital Library; BioMed Central Journals; Cambridge Core; Clinics Collection (Elsevier); JAMA Network (AMA); SciELO, PubMed; Journal Citation Reports (JCR); Latindex: Portal de Portales; Library, among others.

Researchers conducted searches using the descriptors "bioethics," "free and informed consent," "physician," "patient."

**Figure 1.** Flowchart indicating how the selection of articles for the study was carried out




The search on CAPES returned 314 articles; after reviewing the titles and abstracts to verify relevance to the research topic, 92 studies were selected, and 222 were excluded, of which 108 were duplicates. In the analysis of document type, 61 complete studies were excluded, and only articles in Portuguese, English, Spanish, French, and Italian were retained. After excluding the 16 articles in other languages, 15 articles remained for research, whose metadata were used in the bibliometric analysis resulting from the qualitative synthesis.

## Results

The search resulted in 15 articles, detailed in Chart 1.

Of the 15 publications in the sample, most were published in journals. Regarding the language of the publications, five are in Portuguese, four in English, two in French, two in Italian, and three in Spanish.

**Chart 1.** Articles searched

| Authorship; year | Title | Publication | Design | Intervention | Outcome |
|---|---|---|---|---|---|
| Castro and collaborators; 2020 [1] | *Termo de consentimento livre e esclarecido na assistência à saúde* | *Revista Bioética* | Quantitative: cohort study | Five-year intervention | The authors selected articles focusing on the ICF and noticed difficulties faced by the healthcare team in its use, mainly related to the objective and language, as well as the way it is presented, due to socioeconomic factors. |
| Dankar, Gergely, Dankar; 2019 [2] | *Informed consent in biomedical research* | *Computational and Structural Biotechnology Journal* | Quantitative: narrative review | Primary intervention | The authors analyzed ICFs and noted that this is the result of disordered episodes in the clinical and research areas over the last 100 years. |
| Fitriana; 2023 [3] | *The role of informed consent as legal protection for doctors in conducting medical procedures* | *Sinergi International Journal of Law* | Qualitative: empirical legal research | Five-year intervention | The results indicate that informed consent plays a categorical role in the physician-patient relationship, serving as written proof of the agreement between both before medical treatment is performed. |
| Luna; 2008 [4] | *Consentimento livre e esclarecido: ainda uma ferramenta útil na ética em pesquisa* | *Revista Eletrônica de Comunicação, Informação & Inovação em Saúde* | Qualitative: cohort study | Primary intervention | The study detected problems with ICFs because developing countries, due to socioeconomic factors and epistemological problems, present an inappropriate view of research subjects. |
| Makhlou; 2023 [5] | *Le cheminement de l'obligation d'information en droit medical* | *La Revue d'enseignant chercheur des études juridiques et politiques* | Qualitative: empirical legal research | Five-year intervention | In medical law, the obligation to inform the patient must be detailed regarding probable risks, to allow for fully informed consent. |

continues...

**Chart 1.** Continuation

| Authorship; year | Title | Publication | Design | Intervention | Outcome |
|---|---|---|---|---|---|
| O'Neill; 2003 [6] | *Some limits of informed consent* | *Journal of Medical Ethics* | Quantitative: literature review | Quaternary intervention | The study compiles reports on the ICFs that support individual autonomy. However, this presents diverse understandings and the ethical importance varies according to socioeconomic factors, continent, and country under analysis. |
| Baia; 2022 [7] | *A responsabilidade civil médica: o consentimento informado nos ordenamentos jurídicos português e brasileiro* | Master's thesis | Narrative review | Five-year intervention | The study analyzed the legal protection attributed to the ICF, verifying its legal validity in critical procedures, with case law related to the legal responsibility of physicians through the signing of the form. |
| Canivet; 2015 [8] | *Le préjudice d'impréparation: un nouveau poste de préjudice en droit belge. Consentement du patient, manquement au devoir d'information du médecin* | Master's thesis | Qualitative: empirical legal research | Five-year intervention | The study noted that patient consent occupies a central place in the law of medical responsibility and in case law in France, being essential for the practice of the medical act, in addition to the fact that legal concepts include information and the patient's right to freedom and informed consent. |
| Cartagena-Torres and collaborators; 2021 [9] | *Validación de un instrumento para la evaluación del consentimiento informado y su uso en investigación en estudiantes universitarios* | *Ciencia y Tecnología para la Salud Visual y Ocular* | Qualitative: cohort study | Five-year intervention | The results found that professionals with expertise in bioethics opined on the developed instrument and concluded that, in Kendall's analysis, there is statistically significant agreement in the indicators of coherence, clarity, and relevance ($p < 0.001$). |

continues...

**Chart 1.** Continuation

| Authorship; year | Title | Publication | Design | Intervention | Outcome |
|---|---|---|---|---|---|
| Glaser and collaborators; 2020 [10] | *Interventions to improve patient comprehension in informed consent for medical and surgical procedures: an updated systematic review* | *Medical Decision Making* | Qualitative: systematic review | Primary intervention | The study evaluated the results of interventions to improve patient understanding of informed consent and found statistically significant progress. Eighty-five percent of the studies (44/52) demonstrated understanding of the risks; 69% (41/52), of the procedure; 35% (18/52), of the benefits; and 31% (16/52), of the options. |
| Lima; 2016 [11] | *O desenvolvimento histórico da teoria do consentimento informado no Brasil e na Espanha* | *civilistica.com* | Qualitative: empirical legal research | Five-year | The study conducted a comparative analysis of the Brazilian and Spanish models on ICFs, demonstrating that in Brazil the first manifestations are linked to medical experiences and in Spain the physician-patient relationship is a consequence of the direct medical act. |
| Matuk; 2023 [12] | *Il "rito" del consenso informato e il principio di autonomia* | *Rivista della Società Italiana di Antropologia Medica* | Quantitative: narrative review | Five-year intervention | The results indicate the limits and possibilities of ICF, demonstrating that bioethical discourse is embedded in practice that goes beyond bureaucracy, as well as that ICF functions as a tool for changing patient behavior, even with socioeconomic factors. |
| Napoletano; 2020 [13] | *Consenso informato: il diritto all'autodeterminazione del paziente e la responsabilità civile del medico* | *Ius in itinere* | Qualitative: empirical legal research | Five-year intervention | The study indicates the evolution of the concept of the ICF based on Italian case law, highlighting the importance now attributed to the obligation of healthcare providers to provide information to patients. |

continues...

**Chart 1.** Continuation

| Authorship; year | Title | Publication | Design | Intervention | Outcome |
|---|---|---|---|---|---|
| Ribeiro, Assis; 2023 [14] | *Responsabilidade civil médica e a indispensabilidade do consentimento informado* | *RECIMA21* | Empirical-legal research | Primary intervention | The results reveal the accuracy of the ICF, emphasizing its auxiliary function for physicians and patients. |
| Yágüez; 2002 [15] | *Consentimiento informado: algunas reflexiones sobre la relación de causalidad y el daño* | 2° Congreso de la Asociación Española de Abogados Especializados en Responsabilidad Civil y Seguro | Qualitative: editorial | Five-year intervention | The study analyzed several judgments related to informed consent in the Spanish legal context, concluding that the ICF is a contractual relationship between physician and patient, with prior information initiated exclusively by the physician being a prerequisite for the patient to give their consent. |

Articles in various languages were selected to reduce bias. The selected publications were published between 2002 and 2023: in 2002, one article in Spanish; in 2003, one article in English; in 2008, one article in Portuguese; in 2015, one article in French; in 2016, one article in Spanish; in 2019, one article in English; in 2020, three articles—one in Portuguese, one in English, one in Italian; in 2021, one article in Spanish; in 2022, one article in Portuguese; and in 2023, four articles—one in English, one in Italian, one in French and one in Portuguese.

Next, the results of each study are highlighted by year and language of publication. In English, four studies were analyzed. In 2023, Fitriana [3] found that informed consent plays a categorical role in the physician-patient relationship, serving in the Judiciary as written proof of agreement between both .

Glaser and collaborators [10] conducted an updated systematic review in 2020 to assess the results of interventions to improve patient understanding of informed consent. Statistically significant progress was detected: 85% of the studies (44/52) demonstrated patients' understanding of the risks; 69% (41/52) of the procedure; 35% (18/52) of the benefits; and 31% (16/52) of the options.

In 2019, Dankar, Gergely, and Dankar [2] noted that informed consent emerged from disordered episodes in the clinical and research areas over the last 100 years. The last English-language study was by O'Neill [6] in 2003, which compiles reports on informed consent in medical ethics. According to the author, these reports are valuable because they support individual autonomy, but this concept presents diverse understandings and its ethical importance varies across socioeconomic factors, as well as the continents and countries under analysis.

Four analyzed studies were published in Portuguese. In 2023, Ribeiro and Assis [14] reported results demonstrating the accuracy of informed consent, highlighting its auxiliary role for physicians and patients. Baia [7], in 2022, analyzed the legal protection of the informed consent form and its validity in critical procedures, and presented judged cases on the legal responsibility of physicians upon signing the form. In 2020, Castro and collaborators [1]

selected articles that focus on the form and the observed difficulties healthcare teams face in its use, mainly related to its purpose and language, as well as the way it is presented, due to socioeconomic factors.

Finally, in 2008, Luna [4] identified problems in ICF in developing countries which, due to socioeconomic factors and epistemological issues, present an inappropriate view of research subjects, that is, physicians and patients.

The French language contributed two articles to the research. In 2023, Makhlou [5] concluded that, in medical law, the obligation to inform the patient must be detailed regarding probable risks to allow fully informed consent. In 2015, Canivet [8] observed that patient consent occupies a central place in medical liability law and in current jurisprudence in France, being essential to the practice of the medical act, and that legal concepts include information and the patient's right to freedom and informed consent.

The Italian language also contributed two articles. In 2023, Matuk [12] analyzed the limits and possibilities of the ICF, grounded in the principle of autonomy, and demonstrated how bioethical discourse is embedded in practice that goes beyond bureaucracy, functioning as a tool for changing patient behavior, even in the face of socioeconomic factors. In turn, Napoletano [13], in a 2020 study, identified the evolution of the concept of informed consent in Italian case law, highlighting the importance now attributed to the healthcare provider's obligation to provide information to the patient.

Three articles in Spanish were analyzed. In the 2021 study by Cartagena-Torres and collaborators [9], results highlgihted that professionals with bioethics training opined on a developed instrument and concluded, in Kendall's analysis, that there is statistically significant agreement in coherence, clarity, and relevance indicators ($p < 0.001$).

In 2016, Lima [11] carried out a comparative analysis of the Brazilian and Spanish models of the Informed Consent Form. His results show that in Brazil, the first manifestations about the ICF are linked to medical experiences, whereas in Spain, the physician-patient relation is a consequence of the direct medical act.

Yágüez [15] analyzed several sentences related to the Informed Consent Form in the Spanish legal context, concluding that the ICF constitutes a contractual relationship between the physician and the patient, with prior information provided exclusively by the physician as a prerequisite for proof in the Judiciary.

## Discussion

This topic discusses the selected authors' opinions on medical policy, socioeconomic factors, critical care, and the jurisprudence of the countries where the studies were conducted, along with their discussions and conclusions.

Canivet [8] states that, while previously it was exceptional to invoke a lack of information due to socioeconomic factors, currently informed consent as support for medical liability action is commonplace, which was confirmed by Makhlou [5], according to whom, in medical law, information to the patient must be meticulous regarding the risks so that they can give informed consent.

In turn, Castro and collaborators [1] understand that bioethics holds autonomy as one of its principles, which underlies informed consent, as evidenced by the informed consent form. The document has been used to provide legal protection for healthcare professionals, mainly physicians, in cases of technical error, which goes against the initial proposal. The physician-patient relationship is considered one of trust and cooperation, i.e., a contract. In this relationship, the physician is the contractor, and the patient is the client. The author concludes that the ICF, if used correctly, provides the professional with legal protection in cases of lawsuits filed by the patient or their family members, which was supported by Fitriana [3], who recognizes the ICF as an agreement between physician and patient and understands that the transactions take the form of informed consent involving the physician, who explains to the patient their condition and the medical procedures to achieve recovery. In conclusion, informed consent serves as a basis

for determining whether the patient accepts medical treatment, thereby protecting the physician and providing a defense against possible claims or lawsuits if the medical procedure has unintended consequences.

In contrast, Luna [4] argues that the ICF is associated with common cases of research ethics, understanding that the spontaneous environment cannot be evaluated in relation to socioeconomic factors, as this is an unavoidable problem in developing countries, and that the ICF must be improved to avoid disconnection and misalignment in its configuration.

A similar view is held by Dankar, Gergley, and Dankar [2], who argue that the notion of informed consent has changed as a result of advances in medicine, socioeconomic factors, and the types of data collected. Thus, informed consent is misaligned with the objectives of medical research, and it is vital to approach this abyss and begin building new structures to bridge this disconnection.

O'Neill [6] states that informed consent provides patients with assurances that they will not be deceived or coerced. Consent is understood as an intransitive act, and that complete consent is an illusion, given that the objective of consent is to avoid deception and coercion and to give patients control over the amount of information they receive and the opportunity to rescind the consent already given.

This understanding is supported by Glaser and collaborators [10], who state that, under current practices, patient understanding is insufficient or inadequate for informed consent to be valid. Future studies should emphasize the key elements of informed consent and explore its effects among vulnerable populations.

Baia [7] states that the form serves as proof to the physician that the patient has agreed to the expressed terms. Thus, the patient has the right to free will, including the right to refuse treatment, which removes the physician's responsibility for an outcome that harms the patient's health and life. Even if the physician does not agree with the decision, they cannot perform any procedure against the patient's will or at the request of relatives when the patient is in a condition of discernment.

Matuk [12] supports Baia's opinion [7] by stating that there is a degree of autonomy necessary to sign the informed consent form, out of respect for the patient, in addition to exposing an ethical dilemma, the principle of autonomy, also demonstrating that the bioethical discourse must be included in the ICF functioning as an instrument of change.

Napoletano [13] understands that informed consent is the patient's right to be informed about their health conditions and to freely choose whether to undergo treatment; in addition, informing the patient it is a medical obligation, and its violation leads to civil liability. The Court of Cassation's jurisprudence is consolidated by imputing to the physician responsibility for violating the duty to inform and by recognizing the patient's right to compensation for damages resulting from such a violation.

This opinion is reaffirmed by Ribeiro and Assis [14], who, in their analysis of the categories of civil liability in Brazilian law, include aspects such as informed consent, contributing to a deeper understanding of informed consent in the medical field and offering important perspectives for healthcare professionals.

In turn, Yágüez [15] analyzes the sentences issued in Spain up to the date of the study and agrees with the Supreme Court's decisions, holding that the duty to inform is provided for by law. In conclusion, the jurisprudence has openly established the principle that the patient's freedom of decision is a right whose violation or ignorance on the part of the physician constitutes a form of fault or negligence, while Cartagena-Torres and collaborators [9] detected that the core of informed consent is the assignment of the consequences for the lack of information from the physician. The hypothesis referred to is that in which the physician does not provide information, or provides inaccurate information, to the patient about the episode that later becomes the basis for legal action; i.e., the physician's fault is for violating the duty to inform.

Finally, Lima [11] researched the historical trajectory of informed consent accompanying medical practice in its trends in Brazil and Spain and concluded that the development of the theory of informed consent in Spain did not follow the same path as in Brazil, since in Brazil the origins of informed consent lie in medical research and experiments with human beings, while in Spain it is considered a patient's right in the healthcare relationship provided by professionals. The author highlights the separation between the Spanish and Brazilian models of patient protection and safeguarding, mainly due to the lack of specific regulations for informed consent in Brazil.

## Final considerations

This study shows that informed consent plays a role in the legal protection of physicians and patients, serving as a binding agreement between the two parties and establishing a commitment between both. Moreover, it is essential for safeguarding physicians in unforeseen circumstances during procedures, and in the Judiciary, it serves as a basic legal mechanism for protecting patients' rights.

For the form to be valid, physicians must have a thorough understanding of the treatment to be performed, including its risks and benefits. In addition, it is mandatory that physicians interact transparently with patients so that they can make informed choices and exempt themselves from potential liability for lack of information whenever there is a need to intervene in the human body.

The medical act, however well performed, and its professional, however well-intentioned, are not immune to the rules of the Judiciary. It should be noted that, before consent, there must be full and effective information os the clinical procedures to be performed on the patient, or the ICF effectiveness may be nullified. Thus, consent will occur when the patient and their family decides to authorize the clinical procedure, based on the professional's advice, and after signing the ICF according to current health policies, socioeconomic factors, and laws and case laws in force in the country, for the ICF documents all the information provided by the professional and the patient's authorization.

However, there are cases in which the physician's professional conduct, or lack thereof, harms the patient to the point that their health is severely affected or even taken away with death. In these cases, the physician's culpability, if proven, results in liability both before medical boards and in the legal sphere. Given the above, it is possible to conclude that when properly used, the ICF provides the professional, the institution where they work, and the patient with the necessary legal protection.

## References


1. Castro CF, Quintana AM, Olesiak LR, München MAB. Termo de consentimento livre e esclarecido na assistência à saúde. Rev. bioét. (Impr.) [Internet]. 2020 [acesso 29 jul 2025];28(3). DOI: 10.1590/1983-80422020283416
2. Dankar FK, Gergely M, Dankar SK. Informed consent in biomedical research. Comput Struct Biotechnol J [Internet]. 2019 [acesso 29 jul 2025];17:463-74. DOI: 10.1016/j.csbj.2019.03.010
3. Fitriana D. The role of informed consent as legal protection for doctors in conducting medical procedures. Sinergi International Journal of Law [Internet]. 2023 [acesso 29 jul 2025];1(3):235-45. DOI: 10.61194/law.v1i3.101
4. Luna F. Consentimento livre e esclarecido: ainda uma ferramenta útil na ética em pesquisa. RECIIS [Internet]. 2008 [acesso 29 jul 2025];2(1). DOI: 10.3395/reciis.v2i0.866
5. Makhlouf S. Le cheminement de l'obligation d'information en droit médical. La Revue d'Enseignant Chercheur des Études Juridiques et Politiques [Internet]. 2023 [acesso 29 jul 2025];8(1):517-32. Disponível: https://bit.ly/3J3g1Vk

6. O'Neill O. Some limits of informed consent. J Med Ethics [Internet]. 2003 [acesso 29 jul 2025];29(1):4-7. DOI: 10.1136/jme.29.1.4
7. Baia MS. A responsabilidade civil médica: o consentimento informado nos ordenamentos jurídicos português e brasileiro [dissertação] [Internet]. Lisboa: Universidade Autónoma de Lisboa; 2022 [acesso 29 jul 2025]. Disponível: https://bit.ly/4mWviW4
8. Canivet A. Le préjudice d'impréparation: un nouveau poste de préjudice en droit belge. Consentement du patient, manquement au devoir d'information du médecin [dissertação] [Internet]. Louvain: Université Catholique de Louvain; 2015 [acesso 29 jul 2025]. Disponível: https://bit.ly/46WQbKD
9. Cartagena-Torres E, Vargas-Hernández Y, Cuevas-Rodríguez GN, Rubio-Rincón GS. Validación de un instrumento para la evaluación del consentimiento informado y su uso en investigación en estudiantes universitarios. Cienc Tecnol Salud Vis Ocul [Internet]. 2021 [acesso 29 jul 2025];19(2):55-60. DOI: 10.19052/sv.vol19.iss2.7
10. Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M *et al*. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: an updated systematic review. Med Decis Making [Internet]. 2020 [acesso 29 jul 2025];40(2):119-43. DOI: 10.1177/0272989X19896348
11. Lima EPPS. O desenvolvimento histórico da teoria do consentimento informado no Brasil e na Espanha. civilistica.com [Internet]. 2016 [acesso 29 jul 2025];5(2):1-34. Disponível: https://bit.ly/4ohPyCF
12. Matuk VLT. Il "rito" del consenso informato e il principio di autonomia: note di un accesso al campo in una comunità di recupero dalla dipendenza da sostanze. Rivista della Società Italiana di Antropologia Medica [Internet]. 2023 [acesso 29 jul 2025];24(56):193-217. Disponível: https://bit.ly/4mTKCmp
13. Napoletano A. Consenso informato: il diritto all'autodeterminazione del paziente e la responsabilità civile del medico. Ius in itinere [Internet]. 2020 [acesso 29 jul 2025]. Disponível: http://bit.ly/4pNoqvt
14. Ribeiro MC, Assis GB. Responsabilidade civil médica e a indispensabilidade do consentimento informado. RECIMA21 [Internet]. 2023 [acesso 29 jul 2025];4(11). DOI: 10.47820/recima21.v4i11.4432
15. Yágüez RA. Consentimiento informado: algunas reflexiones sobre la relación de causalidad y el daño [Internet]. In: 2° Congreso de la Asociación Española de Abogados Especializados en Responsabilidad Civil y Seguro; 14 nov 2002; Granada. Madrid: Asociación Española de Abogados Especializados en Responsabilidad Civil y Seguro; 2002 [acesso 29 jul 2025]. Disponível: https://bit.ly/4jQuAtD

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