

The Civil Law Aspects of Informed Consent to Medical Procedures

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Abstract

Introduction: Informed consent is a communication process between healthcare providers and patients regarding the medical procedures to be performed. Its aim is to provide sufficient information so that patients can make informed decisions, and it is regulated by various laws and regulations in Indonesia.

Purpose of the Research: The purpose of this research is to analyze the legal position of informed consent from the perspective of Indonesian civil law and to examine the civil law implications that arise if there is a violation of the informed consent principle in medical procedures.

Method of Research: This research uses normative legal methods with legislative and conceptual approaches, analyzing primary, secondary, and tertiary legal materials through literature study, and applying descriptive qualitative analysis.

Results of Research: Research findings indicate that informed consent holds a strong legal position within the perspective of Indonesian civil law, being viewed as a manifestation of a therapeutic agreement that must meet the valid agreement requirements according to the Civil Code (KUHPerdata) and be supported by various regulations. Violations of the principles of informed consent can lead to significant civil legal implications, including claims for damages on the grounds of breach of contract or unlawful acts, cancellation of the therapeutic agreement, liability for breach of professional standards, and claims based on consumer protection law. These implications can involve healthcare professionals and healthcare institutions, with consequences that include payment of material and immaterial damages, the burden of proof in court, and impacts on reputation and medical practice.

Keywords: Informed Consent; Civil Law; Therapeutic Agreement; Legal Implications; Legal Responsibility.

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INTRODUCTION

Health is a human right and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in Pancasila and the 1945 Constitution of the Republic of Indonesia. This is reflected in Article 28H paragraph (1) of the 1945 Constitution which states that everyone has the right to live in physical and mental prosperity, to live, and to get a good and healthy living environment and the right to obtain health services.¹ In order to realize the highest degree of health for the community, health efforts are organized in the form of activities with promotive, preventive, curative, and rehabilitative approaches which are carried out in an integrated, comprehensive, and sustainable manner.²

¹ Ayang Ayu Taufitra and I Gede Agus Kurniawan, "Hak Kepemilikan Komunal Dalam Indikasi Geografis," *JUSTISI* 9, no. 2 (April 12, 2023): 175-89, <https://doi.org/10.33506/jurnaljustisi.v9i2.2307>.

² Fheriyal Sri Isriawaty, "Tanggung Jawab Negara Dalam Pemenuhan Hak Atas Kesehatan Masyarakat Berdasarkan Undang Undang Dasar Negara Republik Indonesia Tahun 1945," *Legal Opinion* 3, no. 2 (2015).

One important aspect of organizing health efforts is the relationship between health workers and patients. This relationship is based on the patient's trust in health workers who have expertise in the health sector. However, along with the times and public awareness of their rights, the relationship between health workers and patients has shifted from a paternalistic relationship to a more egalitarian and contractual relationship.³

In the context of this more equal relationship, the concept of informed consent emerged. Informed consent is a process of communication between health workers and patients regarding the medical treatment to be performed, including an explanation of the diagnosis, purpose of medical treatment, alternatives, risks, prognosis, and estimated cost of treatment. This process aims to provide sufficient information to patients so that they can make informed decisions about the medical treatment they will undergo.⁴

The concept of informed consent has been regulated in various laws and regulations in Indonesia. Law Number 36 of 2009 concerning Health, in Article 56 paragraph (1) states that every person has the right to accept or reject part or all of the help that will be given to him after receiving and understanding complete information about the action. Furthermore, Law Number 29 of 2004 concerning Medical Practice, in Article 45 paragraphs (1) to (3) stipulates that every medical or dental action to be performed by a doctor or dentist on a patient must obtain consent, which is given after the patient receives a complete explanation.⁵

Regulation of the Minister of Health Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions also specifically regulates informed consent. This regulation provides more detailed guidelines regarding the process of providing information and consent for medical treatment, including the form and content of the medical treatment consent form.⁶ Despite being regulated in various laws and regulations, the implementation of informed consent in medical practice still faces various challenges. One of the main challenges is the gap in understanding between health workers and patients regarding the medical information conveyed. This can be caused by various factors, such as differences in educational background, limited consultation time, or the use of medical terms that are difficult for ordinary patients to understand.

Another challenge in the implementation of informed consent is related to medical emergencies. In emergency situations where medical action must be taken immediately to save the patient's life, the informed consent process may not be completed. The Medical Practices Act has anticipated this by regulating exceptions in Article 45 paragraph (4) which states that consent for medical action is not required in an emergency situation.⁷ The civil law aspect of informed consent becomes increasingly important considering that the relationship between health workers and patients can be categorized as a contractual relationship. From a civil law perspective, informed consent can be seen as a form of agreement between health workers and patients. This agreement must fulfill the conditions

³ Sabungan Sibarani, "Aspek Perlindungan Hukum Pasien Korban Malpraktik Dilihat Dari Sudut Pandang Hukum Di Indonesia," *Justitia et Pax* 33, no. 1 (November 2017), <https://doi.org/10.24002/jep.v33i1.1417>.

⁴ Sabrina Putri Elizar, Maria Tahira Arief, and Rahma Anggita Satia, "Etika Kesehatan Dalam Upaya Persetujuan Tindakan Medis (Inform Consent) Dalam Pelayanan Kesehatan," *Nusantara: Jurnal Pendidikan, Seni, Sains Dan Sosial Humanioral* 1, no. 2 (2023).

⁵ Solihan, "Persetujuan Pasien Terhadap Tindakan Medis Dokter Dari Perspektif Hukum Positif Indonesia," *Jurnal Al-Himayah* 6, no. 1 (2022).

⁶ Dewi Atriani and Ade Yusuf Yulianto, "Kekuatan Hukum Informed Consent Dalam Praktek Euthanasia Di Indonesia," *Risalah Hukum Fakultas Hukum Universitas Mulawarman* 19, no. 2 (2023).

⁷ Christilia G. Wagiu, Erwin G. Kristanto, and Theo Lumunon, "Informed Consent Di Instalasi Gawat Darurat RSUP Prof. Dr. R. D. Kandou Manado," *Jurnal Biomedik (JBM)* 9, no. 1 (March 2017), <https://doi.org/10.35790/jbm.9.1.2017.15321>.

for the validity of the agreement as stipulated in Article 1320 of the Civil Code (KUHPerdara), namely the agreement of the parties, the ability to make an agreement, a certain matter, and a lawful cause.⁸

Given the complexity and dynamics of issues related to informed consent, further research is needed to examine various aspects of related civil law. This research is expected to contribute to the development of a legal framework that is more comprehensive and responsive to the development of medical practices and public expectations. In addition, this research is also expected to provide practical guidance for health workers in applying the principles of informed consent, as well as increasing public understanding of their rights and responsibilities in the context of health services. Based on the explanation of the research background above, research on "Civil Law Aspects of Informed Consent in Medical Actions" is very relevant and important. The problem formulation in this research is: 1) What is the legal position of informed consent in the perspective of Indonesian civil law?; 2) What are the civil law implications that arise in the event of a violation of the principle of informed consent in medical actions?.

METHODS OF THE RESEARCH

This research uses a normative legal research method, which is library legal research or doctrinal legal research. This method was chosen because this research aims to examine and analyze aspects of civil law in informed consent in medical actions based on existing legal norms in legislation and relevant legal doctrines. The approaches used in this research are statute approach and conceptual approach. The statutory approach is carried out by reviewing all laws and regulations relating to the legal issues being addressed, in this case regulations relating to informed consent and civil law. This approach is important to understand the hierarchy and principles in the relevant laws and regulations. Meanwhile, a conceptual approach is used to understand legal concepts relating to informed consent and the civil law aspects that surround it. This approach is carried out by examining the views and doctrines that have developed in law, especially in the fields of health law and civil law. The sources of legal materials used in this research consist of primary, secondary, and tertiary legal materials. Primary legal materials include relevant laws and regulations, such as the Civil Code, Law Number 36 of 2009 on Health, Law Number 29 of 2004 on Medical Practice, and Minister of Health Regulations related to informed consent. Secondary legal materials include textbooks, legal journals, research results, and opinions of legal experts related to the research topic. Meanwhile, tertiary legal materials include legal dictionaries, encyclopedias, and other sources that can provide guidance or explanation of primary and secondary legal materials. Data collection techniques in this research are carried out through literature studies or document studies. Researchers will collect and review various literature, documents, and other written materials related to the research topic. This process includes searching for legal materials in libraries, legal documentation centers, and credible online sources. In addition, researchers will also conduct an inventory of laws and regulations relevant to the research topic. The data analysis technique used in this research is qualitative analysis with descriptive analytical method. The analysis process begins with organizing the legal materials that have been collected. Furthermore, the researcher will interpret the legal materials to understand their meaning and implications for the civil law aspects of informed consent. The analysis will also involve a process of categorization and

⁸ I Putu Maha Widharta and I Gede Agus Kurniawan, "Perlindungan Hak Cipta Bagi Pencipta Komik Berbentuk Aplikasi Dalam Telepon Pintar," *Jurnal Kertha Semaya* 9, no. 9 (2021): 1676–87, <https://doi.org/https://doi.org/10.24843/KS.2021.v09.i09.p17>.

synthesis to identify patterns, relationships, and themes that emerge from the legal materials studied. In the analysis process, the researcher will use deductive and inductive reasoning methods. Deductive reasoning was used to draw conclusions from general principles of civil law and informed consent into specific cases. Meanwhile, inductive reasoning is used to identify general principles from the analysis of specific cases and existing regulations. The results of the analysis will be presented in the form of a systematic and logical descriptive description, taking into account the coherence between the various aspects studied. The researcher will present the research findings, interpret them in the context of civil law and medical practice in Indonesia, and provide strong legal arguments to support the research conclusions.

RESULTS AND DISCUSSION

A. The Legal Position of Informed Consent in the Perspective of Indonesian Civil Law

The legal position of informed consent in the perspective of Indonesian civil law can be understood through an in-depth analysis of the various legal aspects that surround it. Informed consent, or consent to medical treatment, is one of the important elements in the relationship between health workers and patients. In the context of Indonesian civil law, informed consent has a unique position because it is at the intersection of treaty law and consumer protection law, with special nuances derived from the special characteristics of the health worker-patient relationship.⁹ To understand the legal position of informed consent, it is necessary to refer to the Theory of Therapeutic Agreement. This theory explains that the relationship between health workers and patients is basically a therapeutic agreement, namely an agreement between health workers and patients to seek or provide medical services. In this context, informed consent can be seen as a manifestation of the therapeutic agreement.¹⁰

Therapeutic agreements, like agreements in general, must fulfill the conditions for the validity of the agreement as stipulated in Article 1320 of the Civil Code (KUHPerdata).¹¹ These conditions include: agreement of the parties, capacity to make an agreement, a certain thing, and a halal cause. In the context of informed consent, the agreement of the parties is reflected in the consent given by the patient after obtaining complete information from the health worker.¹² However, therapeutic agreements have specific characteristics that distinguish them from agreements in general. One of the main characteristics is that this agreement falls under the category of *inspanningsverbintenis*, which is a business agreement, not *resultaatsverbintenis* or a result agreement. This means that the health worker does not promise a certain result, but rather promises to make the best effort in accordance with the standards of the medical profession.¹³

The position of informed consent in Indonesian civil law is also strengthened by various laws and regulations. Law Number 29 of 2004 concerning Medical Practice, in Article 45

⁹ Achmad Busro, "Aspek Hukum Persetujuan Tindakan Medis (Informed Consent) Dalam Pelayanan Kesehatan," *Law, Development and Justice Review* 1, no. 1 (November 2018): 1-18, <https://doi.org/10.14710/ldjr.v1i1.3570>.

¹⁰ Anggun Rezki Pebrina, Johni Najwan, and Evalina Alissa, "Fungsi Penerapan Informed Consent Sebagai Persetujuan Pada Perjanjian Terapeutik," *Zaaken: Journal of Civil and Business Law* 3, no. 3 (November 2022), <https://doi.org/10.22437/zaaken.v3i3.18966>.

¹¹ I Gusti Bagus Yudas Swastika et al., "Misuse of Personal Data as a Crime from a Cyber Law Perspective," *Pena Justitia: Media Komunikasi Dan Kajian Hukum* 22, no. 2 (2023): 81-93, <https://doi.org/http://dx.doi.org/10.31941/pj.v22i2.3073>.

¹² Mudiana Permata Sari and Bayu Wijanarko, "Tinjauan Yuridis Sahnya Perjanjian Terapeutik Dan Perlindungan Hukum Bagi Pasien," *Priwat Law* 2, no. 4 (2014).

¹³ Degdy Chandra B. Simarmata, Muhammad Saddam Kennedy, and Lestari Victoria Sinaga, "Analisis Hukum Tentang Perjanjian Terapeutik Antara Dokter Dengan Pasien Dalam Pelayanan Kesehatan," *Jurnal Rectum: Tinjauan Yuridis Penanganan Tindak Pidana* 4, no. 1 (2022), <https://doi.org/http://dx.doi.org/10.46930/jurnalrectum.v4i1.1458>.

paragraphs (1) to (3), stipulates that every medical or dental action to be performed by a doctor or dentist on a patient must obtain consent. This approval is given after the patient receives a complete explanation. The explanation at least includes the diagnosis and procedure of medical action, the purpose of the medical action performed, other alternative actions and their risks, risks and complications that may occur, and the prognosis of the action performed.¹⁴

Moreover, Law No. 36/2009 on Health, in Article 56 paragraph (1), emphasizes that every person has the right to accept or reject part or all of the aid that will be given to him after receiving and understanding complete information about the action. This provision strengthens the position of informed consent as a patient's right that is protected by law.¹⁵ Minister of Health Regulation Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions provides more detailed guidelines regarding the implementation of informed consent. This regulation regulates the procedures for providing information and consent to medical treatment, including the form and content of the medical treatment consent form.¹⁶

In the perspective of civil law, informed consent can be seen as a form of legal protection for both parties, both health workers and patients. For the patient, informed consent is a form of respect for the patient's autonomy to determine what is best for him or her. This is in line with the principles of consumer protection as stipulated in Law Number 8 of 1999 concerning Consumer Protection,¹⁷ in particular the right of consumers to obtain correct, clear and honest information regarding the conditions and guarantees of goods and/or services.¹⁸

For health workers, informed consent can serve as evidence that there has been an agreement between health workers and patients regarding the medical action to be taken. In the event of a medical dispute in the future, the informed consent document can be an important piece of evidence that shows that the health worker has carried out their obligation to provide information and obtain the patient's consent before carrying out medical action.¹⁹ However, the existence of an informed consent document alone is not always sufficient to exempt health workers from legal liability. In the perspective of civil law, especially agreement law, the contents of the agreement (in this case, informed consent) must be implemented in good faith as stipulated in Article 1338 paragraph (3) of the Civil Code. This means that even though there is an informed consent document, health workers are still obliged to carry out medical actions in accordance with professional standards and standard operating procedures.²⁰

Furthermore, in the context of civil law, violations of the principles of informed consent can have legal consequences. Patients who feel harmed due to the non-implementation of

¹⁴ Cut Sidrah Nadira and Cut Khairunnisa, "Kedudukan Informed Consent Dalam Pelayanan Kesehatan Di Indonesia," *Cendekia: Jurnal Hukum, Sosial Dan Humaniora* 1, no. 1 (2023).

¹⁵ William Suntana, "Kajian Tentang Informed Consent (Persetujuan Tindakan Medik) Menurut Uu No. 36 Tahun 2009 Tentang Kesehatan," *Lex Privatum* 5, no. 5 (2017).

¹⁶ Kusnadi Kusnadi, "Persetujuan Tindakan Kedokteran (Informed Consent) Dalam Prespektif Hukum," *Journal Iuris Scientia* 1, no. 1 (January 2023): 36-44, <https://doi.org/10.62263/jis.v1i1.10>.

¹⁷ Anak Agung Sagung Istri Ratu Agung Pratiwi Ningrat and I Gede Agus Kurniawan, "Digital Business Problems and Regulations in an Integrative Legal Perspective," *Syah Kuala Law Journal* 7, no. 2 (2023): 141-56.

¹⁸ Busro, "Aspek Hukum Persetujuan Tindakan Medis (Informed Consent) Dalam Pelayanan Kesehatan."

¹⁹ Rezki Pebrina, Najwan, and Alissa, "Fungsi Penerapan Informed Consent Sebagai Persetujuan Pada Perjanjian Terapeutik."

²⁰ Friska Realita, Agnes Widanti, and Daniel Budi Wibowo, "Implementasi Persetujuan Tindakan Medis (Informed Consent) Pada Kegiatan Bakti Sosial Kesehatan Di Rumah Sakit Islam Sultan Agung Semarang," *Soepra* 2, no. 1 (January 2017): 30, <https://doi.org/10.24167/shk.v2i1.807>.

proper informed consent can file a civil lawsuit on the basis of default or tort. A tort claim can be filed if the medical action taken is not in accordance with what has been agreed upon in the informed consent. Meanwhile, a tort claim can be filed if the health worker takes actions that are contrary to their legal obligations, namely the obligation to provide complete information and obtain the patient's consent before carrying out medical actions.²¹

In the context of evidence, Article 1865 of the Civil Code states that every person who argues that he has a right, or in order to assert his own rights or dispute the rights of others, pointing to an event, is required to prove the existence of the right or event. In the case of medical disputes related to informed consent, the burden of proof is generally on the health workers to show that they have carried out the obligation to provide information and obtain proper patient consent.²² The legal position of informed consent is also closely related to the principles in consumer protection law. Law No. 8/1999 on Consumer Protection, although not specifically regulating health services, provides a general framework of consumer rights that can be applied in the context of health services. Principles such as the right to correct, clear, and honest information, as well as the right to choose goods and/or services, are in line with the concept of informed consent in health services.²³

The legal position of informed consent in the perspective of Indonesian civil law is also influenced by developments in technology and medical practice. For example, in the context of telemedicine, which has been growing, especially since the COVID-19 pandemic, questions arise regarding how the principles of informed consent can be applied in remote health services. The Minister of Health Regulation No. 20/2019 on the Implementation of Telemedicine Services Between Health Care Facilities has provided some guidance, but further development is still needed to accommodate various forms of technology-based health services.²⁴

In addition, the issue of personal data protection is also an important aspect in the legal position of informed consent. In the era of big data and artificial intelligence, the use of health data for various purposes, such as medical research or health technology development, is increasing. This raises questions regarding the extent to which patients need to be informed and asked for consent regarding the use of their health data outside the context of direct care. Law No. 11/2008 on Electronic Information and Transactions as amended by Law No. 19/2016, as well as Government Regulation No. 71/2019 on the Implementation of Electronic Systems and Transactions, provide a general legal framework regarding the protection of personal data, but more specific arrangements are still needed regarding the protection of health data in the context of informed consent.²⁵

From the perspective of Therapeutic Agreement Theory, the legal position of informed consent can be understood as an integral part of the agreement between health workers and patients. Informed consent is not just an administrative formality, but rather a continuous communication process between health workers and patients. This process reflects the principle of patient autonomy and the ethical obligation of health workers to respect the

²¹ Deni Atmaja et al., "Konservasi Hukum Terhadap Hak Pasien Sebagai Konsumen Dalam Pelayanan Medis Di Rumah Sakit Umum," *Jurnal Kesehatan Tambusai* 5, no. 2 (2024), <https://doi.org/https://doi.org/10.31004/jkt.v5i2.27135>.

²² Octavianus M. Momuat, "Alat Bukti Tulisan Dalam Pemeriksaan Perkara Perdata Di Pengadilan," *Lex Privatum* 2, no. 1 (2014).

²³ Atmaja et al., "Konservasi Hukum Terhadap Hak Pasien Sebagai Konsumen Dalam Pelayanan Medis Di Rumah Sakit Umum."

²⁴ Bheti Widyastuti, "Kajian Pidana Kerja Sosial Ditinjau Dari Segi Sosiologi Hukum," *Pascasarjana Hukum UNS* 8, no. 2 (2020): 56-63.

²⁵ Cashtry Meher, Redyanto Sidi, and Irsyam Risdawati, "Penggunaan Data Kesehatan Pribadi Dalam Era Big Data: Tantangan Hukum Dan Kebijakan Di Indonesia," *Jurnal Ners* 7, no. 2 (July 2023): 864-70, <https://doi.org/10.31004/jn.v7i2.16088>.

patient's rights in medical decision-making.²⁶ In this context, informed consent can be seen as an instrument that bridges the information gap between health workers and patients. Health workers, with their medical knowledge and expertise, have an obligation to provide sufficient and understandable information to patients. Meanwhile, patients have the right to receive such information and make decisions based on their understanding.²⁷

The legal position of informed consent in the perspective of Indonesian civil law also reflects a paradigm shift in the health worker-patient relationship. From a paternalistic model where health workers are considered to always know what is best for the patient, it has now shifted to a more egalitarian model where patients are actively involved in medical decision-making. This shift is in line with the development of the understanding of human rights and patient rights.²⁸

Thus, it can be concluded that the legal position of informed consent in the perspective of Indonesian civil law is very strong and multidimensional. Informed consent is not only a manifestation of the therapeutic agreement between health workers and patients, but also an instrument of legal protection for both parties. Informed consent reflects fundamental principles in civil law, such as freedom of contract and good faith, while still taking into account the specific characteristics of the health worker-patient relationship. Despite the existence of various laws and regulations governing informed consent, developments in technology and medical practice continue to raise new challenges that require adjustments and development of the existing legal framework.

B. Comparison of Legal Regulations for Online Buying and Selling Between Malaysia and Singapore

The civil law implications arising from violations of the principle of informed consent in medical actions can be analyzed through the perspective of the Therapeutic Agreement Theory. This theory views the relationship between health workers and patients as a form of agreement that has special characteristics in the field of health services. This therapeutic agreement is based on two fundamental human rights, namely the right to self-determination and the right to information.²⁹

In the context of Indonesian law, this therapeutic agreement can be categorized as a form of agreement to perform certain services as regulated in Article 1601 of the Civil Code (KUHPerdata). However, this agreement has special characteristics that distinguish it from agreements in general, namely the object is an effort (inspanning verbintenis) to cure the patient, not a definite result (resultaat verbintenis).³⁰ Informed consent is one of the key elements in a therapeutic agreement. Law Number 29 of 2004 concerning Medical Practice, in Article 45 paragraphs (1) to (3), regulates that every medical or dental action to be performed by a doctor or dentist on a patient must obtain consent. This approval is given after the patient has received a complete explanation of the objectives and prospects for

²⁶ Chandra Akbar Eka Pratama and Ngadino Ngadino, "Kedudukan Informed Consent Sebagai Perlindungan Hukum Hubungan Dokter Dan Pasien Dalam Kasus Malpraktek," *Notarius* 15, no. 1 (April 2022): 241–52, <https://doi.org/10.14710/nts.v15i1.46038>.

²⁷ Mutia Filia, "Aspek Hukum Persetujuan Tindakan Medis (Informed Consent) Dalam Penerapan Teknik Operasi Bedah Jantung," *Esensi Hukum* 1, no. 1 (December 2019): 96–108, <https://doi.org/10.35586/esensihukum.v1i1.15>.

²⁸ Eka Pratama and Ngadino, "Kedudukan Informed Consent Sebagai Perlindungan Hukum Hubungan Dokter Dan Pasien Dalam Kasus Malpraktek."

²⁹ Iwan Riswandie and Afif Khalid, "Kepastian Hukum Terhadap Perjanjian Terapeutik (Studi Terhadap Pasal 1320 KUHPerdata)," *Prosiding Hasil-Hasil Penelitian Dosen-Dosen Universitas Islam Kalimantan*, 2023, <https://doi.org/http://dx.doi.org/10.31602/ppdu.v0i1.13870>.

³⁰ Rozi Oktri Novika, Mardalena Hanifah, and Ulfia Hasanah, "Kedudukan Hukum Perjanjian Terapeutik (Antara Rumah Sakit Dan Pasien) Dalam Persetujuan Tindakan Medik Menurut Kitab Undang-Undang Hukum Perdata," *Jurnal Online Mahasiswa Fakultas Hukum Universitas Riau* 2, no. 1 (2015).

success of the action to be taken, the procedure for action, the risks and complications that may occur, and other alternative actions available.³¹

Violation of the informed consent principle can have various civil law implications. First, this violation can be considered as a form of default or breach of promise in the context of a therapeutic agreement. Based on Article 1239 of the Civil Code, in the event of a default on an obligation to do something, the creditor (in this case the patient) has the right to demand reimbursement of costs, losses and interest. In the context of health services, this can mean that the patient has the right to claim compensation for the losses he has suffered due to medical actions carried out without proper informed consent.³² Second, violations of the principle of informed consent can also be categorized as unlawful acts as stipulated in Article 1365 of the Civil Code. This article states that every act that is unlawful and brings harm to another person, obliges the person who causes the harm through his fault to compensate for the loss. In this context, medical actions performed without proper informed consent can be considered as a violation of the patient's right to self-determination, which is a right protected by law.³³

Another civil law implication relates to evidentiary issues. In the event of a dispute, the burden of proof is generally on the health worker to show that they have carried out their obligation to provide information and obtain proper patient consent. This is in accordance with the principle of proof in civil law as stipulated in Article 1865 of the Civil Code. Therefore, good documentation of the informed consent process is very important as evidence in court. In the context of compensation, violation of the principle of informed consent may result in health workers being required to provide compensation to patients. This compensation may include material and immaterial losses. Material losses can be in the form of additional medical expenses that must be borne by the patient due to complications from medical actions that he did not agree to. Meanwhile, immaterial loss can be in the form of psychological suffering or loss of opportunity to choose other treatment alternatives.³⁴

Law No. 36/2009 on Health, in Article 58, also regulates the patient's right to claim compensation against a person, health worker, and/or health provider who causes harm due to errors or negligence in the health services received. Violation of the principle of informed consent can be considered as a form of negligence in health services.³⁵ In addition, violation of the principle of informed consent can also result in the invalidation of the therapeutic agreement. Based on Article 1320 of the Civil Code, one of the conditions for the validity of an agreement is the agreement of the parties. If informed consent is not properly implemented, it can be argued that there is no valid agreement between the health worker and the patient regarding the medical action taken. Consequently, the therapeutic agreement can be canceled.³⁶

³¹ Rezki Pebrina, Najwan, and Alissa, "Fungsi Penerapan Informed Consent Sebagai Persetujuan Pada Perjanjian Terapeutik."

³² Sandra Dini Febri Aristya, "Pembuktian Perdata Dalam Kasus Malpraktik Di Yogyakarta," *Mimbar Hukum - Fakultas Hukum Universitas Gadjah Mada*, February 2012, 180, <https://doi.org/10.22146/jmh.16166>.

³³ Widodo Tresno Novianto, "Penafsiran Hukum Dalam Menentukan Unsur-Unsur Kelalaian Malpraktek Medik (Medical Malpractice)," *Yustisia Jurnal Hukum* 4, no. 2 (August 2015), <https://doi.org/10.20961/yustisia.v4i2.8670>.

³⁴ Zul Aida, Ardiansah, and Indra Afrita, "Tanggung Jawab Hukum Dokter Dalam Tindakan Operasi Pembedahan Dari Perspektif Hukum Indonesia," *Innovative: Journal Of Social Science Research* 4, no. 1 (2024), <https://doi.org/https://doi.org/10.31004/innovative.v4i1.9580>.

³⁵ Jeveline Mende, "Perlindungan Hukum Terhadap Pasien Rawat Inap Sebagai Konsumen Jasa Pelayanan Kesehatan," *Lex Administratum* 11, no. 5 (2023).

³⁶ Christiana Jullia Makasengehe, "Aspek Hukum Transaksi Terapeutik Antara Tenaga Medis Dengan Pasien," *Lex Privatum* 12, no. 1 (2023).

Another civil law implication relates to the issue of liability. In the context of a therapeutic agreement, health workers have an obligation to carry out health services in accordance with professional standards and standard operating procedures. Violation of the principle of informed consent can be considered a violation of professional standards, which may result in health workers being held civilly liable for losses incurred.³⁷ Regulation of the Minister of Health Number 290/MENKES/PER/III/2008 on the Approval of Medical Actions specifically regulates informed consent. Violation of the provisions in this regulation can be the basis for claiming civil liability of health workers. For example, if a health worker does not provide sufficient information as stipulated in Article 7 paragraph (3) of the regulation, this can be considered as negligence that gives rise to civil liability.³⁸

In the context of consumer protection law, patients can be considered as consumers of health services. Law No. 8/1999 on Consumer Protection gives consumers the right to obtain correct, clear, and honest information regarding the condition and guarantee of goods and/or services. Violation of the principle of informed consent can be considered a violation of this consumer right, which may result in a claim for compensation under consumer protection law.³⁹

Another civil law implication relates to the issue of confidentiality of patient data. In the informed consent process, health workers obtain personal and sensitive information about the patient. Violation of the confidentiality of this information may result in claims for damages on the basis of invasion of privacy. This is increasingly relevant with the enactment of Law Number 11 of 2008 concerning Electronic Information and Transactions as amended by Law Number 19 of 2016, which regulates the protection of personal data.⁴⁰ In the context of the development of health technology, such as the use of telemedicine, the civil law implications of violating the principle of informed consent are becoming increasingly complex. Minister of Health Regulation Number 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Care Facilities has regulated several aspects related to informed consent in telemedicine services. Violation of these provisions may lead to civil liability for telemedicine providers.⁴¹

The civil law implications of violating the principle of informed consent can also extend to health care institutions. Based on the doctrine of respondeat superior, hospitals or clinics can be held liable for the actions of health workers working under their auspices. This means that health care institutions can also face compensation claims due to violations of the principle of informed consent committed by their health worker.⁴² In addition, violations of the principle of informed consent can have an impact on the reputation and public trust in health workers or health care institutions. While this is not a direct legal implication, it can have significant economic consequences in the long run.

³⁷ Adi Tio Helga Ramanda, "Tanggung Jawab Hukum Dokter Terhadap Konsultasi Via Online Apabila Pasien Mengalami Kerugian," *Yustisia Merdeka : Jurnal Ilmiah Hukum* 7, no. 1 (April 2021): 1–8, <https://doi.org/10.33319/yume.v7i1.73>.

³⁸ Rama Arsa Faisal, Syofirman Syofyan, and Yussy Adelina Mannas, "Persetujuan Tindakan Kedokteran Sebagai Pemenuhan Hak Pasien Pada Pelaksanaan Tindakan Kedokteran Di Rumah Sakit Semen Padang," *Unes Law Review* 5, no. 4 (2023).

³⁹ Didiek Wahyu Indarta, "Perlindungan Hukum Pasien Sebagai Konsumen Jasa Dalam Pelayanan Kesehatan (Studi Di Rumah Sakit Ibnu Sina Bojonegoro)," *Justitiable: Fakultas Hukum Universitas Bojonegoro* 1, no. 2 (2019), <https://doi.org/https://doi.org/10.56071/justitiable.v1i2.48>.

⁴⁰ Eka Pratama and Ngadino, "Kedudukan Informed Consent Sebagai Perlindungan Hukum Hubungan Dokter Dan Pasien Dalam Kasus Malpraktek."

⁴¹ Resita Lukitawati and Widodo Trisno Novianto, "Regulasi Layanan Kesehatan Digital Di Indonesia: Tantangan Etis Dan Hukum," *Ajudikasi : Jurnal Ilmu Hukum* 7, no. 2 (December 2023): 391–414, <https://doi.org/10.30656/ajudikasi.v7i2.7862>.

⁴² Yaumul Chaeria, Dachran Busthami, and Hardianto Djanggih, "Implikasi Kedudukan Tenaga Medis (Informed Consen) Terhadap Pertanggungjawaban Rumah Sakit," *Petitum* 8, no. 1 (2020), <https://doi.org/https://doi.org/10.36090/jh.v8i1%20April.655>.

In the context of medical research, a violation of the informed consent principle may result in the invalidation of the research results and a claim for compensation from the research subject. This is regulated in various ethical guidelines for medical research, including the Declaration of Helsinki which has been widely adopted in Indonesia. Finally, it is worth noting that the civil law implications of violating the principle of informed consent are not limited to the relationship between health workers and patients. In cases where the patient is incapable of giving consent (e.g. due to medical conditions or age), a breach of the informed consent principle may give rise to lawsuits from the patient's family or guardian.

Thus, it can be concluded that violations of the principle of informed consent in medical procedures can have significant civil law implications. These implications include claims for damages on the basis of default or tort, invalidation of therapeutic agreements, liability for breach of professional standards, claims under consumer protection law, as well as consequences related to data confidentiality and reputation. Therefore, it is important for health workers and health care institutions to understand and implement the principle of informed consent properly to avoid adverse legal implications.

CONCLUSION

The legal position of informed consent in the perspective of Indonesian civil law has a strong and multidimensional position. Informed consent is seen as a manifestation of a therapeutic agreement between health workers and patients, which must fulfill the legal requirements of an agreement in accordance with Article 1320 of the Civil Code. This is a form of respect for the patient's autonomy rights and legal protection for both parties. Its position is strengthened by various laws and regulations such as the Medical Practice Act, the Health Act, and the Permenkes on the Approval of Medical Actions. In the context of civil law, informed consent is also related to the principles of consumer protection and can be the basis for claims of default or tort in the event of a violation. Despite its strong legal standing, developments in technology and medical practice continue to raise new challenges that require adjustments to the existing legal framework. Violation of the principle of informed consent in medical actions can lead to various significant civil law implications. Based on the Theory of Therapeutic Agreement and applicable laws and regulations, these implications include: claims for compensation on the basis of default (Article 1239 of the Civil Code) or tort (Article 1365 of the Civil Code), cancellation of the therapeutic agreement due to non-fulfillment of the conditions of agreement (Article 1320 of the Civil Code), liability for violation of professional standards, claims under consumer protection law (Law No. 8 of 1999), as well as consequences related to data confidentiality and reputation. Health workers may be required to pay material and immaterial damages, face the burden of proof in court, and be liable for violations of provisions in Permenkes No. 290/MENKES/PER/III/2008. These implications may also extend to healthcare institutions under the doctrine of respondeat superior, as well as impact on medical research and relationships with patients' families or guardians in certain cases.

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