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The Role of Informed Consent in the Legality and Legal Protection of Medical Personnel

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Abstract

Medical professionals face litigation risks from legal uncertainty in medical procedures, highlighting informed consent as an important legal protection amid rising medical disputes in Indonesia. The purpose of this research is to analyze the role of informed consent in ensuring the legality of medical procedures, examine its legal construction as a basis for excluding criminal liability for medical personnel under Law Number 17 of 2023 concerning Health, and assess its application in digital health services and high-risk medical procedures. The research method used is normative juridical with a statute approach and a conceptual approach. The results of the study indicate that informed consent is not merely an administrative formality, but rather the primary legal basis that transforms invasive procedures into legally valid actions by fulfilling patient autonomy. Legally, informed consent functions as a justification (*rechtvaardigingsgronden*) that eliminates the material unlawfulness of medical procedures, as long as they are carried out according to professional standards and without information defects (vitiated consent). This study concludes that informed consent is an essential preventive legal protection instrument that eliminates criminal culpability through the principle of *volenti non fit iniuria*, provided that medical information is communicated effectively.

Keywords

Health Law, Informed Consent, Legal Contruction, Legal Protection, Medical Personnel.

1. Introduction

Health is a fundamental human right and a key determinant of collective welfare (Putra & Kuswardhani, 2024). In the contemporary healthcare system, legal protection for medical personnel has become increasingly important due to rising public skepticism regarding medical malpractice and treatment outcomes (Firma et al., 2025). The complexity of medical procedures further creates legal uncertainty and anxiety among medical personnel in exercising their clinical authority (Herisasono et al., 2023). Legal protection for medical practitioners in Indonesia is regulated through Law Number 29 of 2004 concerning Medical Practice and strengthened by Law Number 17 of 2023 concerning Health (Kurniawan et al., 2024; Ayudha & Herlambang, 2026). In this framework, informed consent serves as both an ethical obligation and a legal instrument that respects patient autonomy while reducing the risk of legal liability for healthcare professionals (Pont & Immanuel, 2025; Kusumastuti et al., 2025). Its implementation is specifically regulated under Minister of Health Regulation Number 290/Menkes/Per/III/2008 and Article 293 of the Health Law (Sari & Udiana, 2025).

Conceptually, the relationship between medical personnel and patients constitutes a legal relationship that generates reciprocal rights and obligations (Wahyuni & Laskarwati, 2020). Informed consent serves as evidence that the patient has understood and accepted the consequences of a medical procedure after receiving transparent and comprehensive information from the healthcare provider. In contemporary legal discourse, informed consent is no longer perceived merely as an administrative formality but rather as a significant legal instrument that provides protection for medical personnel (Dewi & Adiatmika, 2025). Auliansyah et al. (2025) emphasize that the implementation of informed consent through the perspective of legal certainty theory effectively minimizes disputes between doctors and patients because patients gain a comprehensive understanding of medical procedures and potential risks. Likewise, Gustina et al. (2022) highlight the evidentiary value of informed consent documentation, particularly within the era of digital health information systems, where properly documented consent strengthens the legal standing of healthcare providers during litigation processes.

In the sphere of criminal law, informed consent has also developed as a doctrinal basis for excluding the unlawful nature of medical actions (Thahir & Tongat, 2024). Sastrani (2025) argues that informed consent may function as a *rechtvaardigingsgronden* or justification defense because an invasive medical procedure that objectively fulfills the elements of assault loses its material unlawfulness when performed with valid patient consent. This approach reflects the legal principle of *volenti non fit iniuria*, meaning that no injury exists where a person has voluntarily agreed to the act (Sundari et al., 2022). Consequently, when medical personnel have comprehensively disclosed foreseeable medical risks and the patient has consciously provided approval, the element of criminal culpability (*schuld*) may be excluded, thereby protecting healthcare professionals from criminal malpractice accusations.

Despite its strong normative framework, the practical implementation of informed consent continues to encounter substantial empirical obstacles. Irawati et al. (2020) identify significant communication and health literacy gaps between medical personnel and patients, particularly in translating complex medical terminology into language understandable to non-medical individuals. Inadequate or misleading information may result in a "defect of will" or vitiated consent, rendering the consent legally invalid. From the perspective of criminal law, defective consent cannot serve as a basis for eliminating the unlawful nature of a medical action (Viranda & Zulfiko, 2026). At the same time, the increasing trend of medical litigation in Indonesia further demonstrates the urgency of strengthening informed

consent mechanisms. The rise in medical disputes in Indonesia underscores the importance of informed consent, as disputes often involve inadequate information disclosure, patient misunderstanding, and invalid consent, which may increase legal risks for healthcare professionals and institutions (Susilowati et al., 2021). This problem is exacerbated by the absence of standardized national guidelines for distinguishing agreed medical risks from conduct that may constitute criminal malpractice (Wijaya & Irhamdessetya, 2025).

Although previous studies have examined informed consent primarily from the perspectives of medical ethics, patient autonomy, and dispute prevention, limited attention has been given to its juridical function as a basis for excluding criminal liability in medical practice. Furthermore, there remains a lack of comprehensive legal analysis regarding the relationship between the validity of informed consent and the doctrine of unlawfulness under Law Number 17 of 2023 concerning Health. Based on these circumstances, this research aims to examine informed consent as a fundamental legal instrument in healthcare services, analyze its role in providing legal protection and excluding criminal liability for medical personnel, and evaluate its implementation in the context of digital health services and high-risk medical procedures under Law Number 17 of 2023 concerning Health.

2. Methods

This study employs a normative juridical research method with a doctrinal-analytical approach (doctrinal legal research). The method is selected because the research focuses on examining legal norms, doctrines, and principles governing informed consent as a legal protection instrument for medical personnel and as a basis for excluding criminal liability in healthcare practices. Rather than relying on empirical observation, the study seeks to construct and evaluate legal arguments concerning the juridical position of informed consent within the Indonesian healthcare legal system. To achieve this objective, the research applies a statutory approach (statute approach) to analyze relevant legislation, a conceptual approach (conceptual approach) to examine legal doctrines and theories concerning consent, legal protection, and criminal liability, and a doctrinal approach to assess the legal construction of informed consent within criminal law and health law frameworks.

The study relies on secondary data consisting of three categories of legal materials. Primary legal materials include statutory regulations governing medical practice and healthcare services in Indonesia, particularly Law Number 29 of 2004 concerning Medical Practice, Law Number 17 of 2023 concerning Health, and Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Informed Consent. Secondary legal materials consist of textbooks, peer-reviewed scientific journals, legal commentaries, court-related legal analyses, and previous studies discussing medical law, patient autonomy, legal protection, criminal liability, and informed consent. Tertiary legal materials include legal dictionaries, encyclopedias, and other reference sources used to clarify legal concepts and terminology relevant to the research.

Data collection was conducted through systematic document study techniques involving the identification, classification, inventory, and comprehensive examination of legal materials relevant to the research problem. The collected materials were subsequently organized according to major themes, including the legal validity of informed consent, justification defenses in criminal law, legal protection of healthcare professionals, and patient rights within healthcare services.

The analysis was conducted using qualitative doctrinal analysis through legal interpretation and normative reasoning. Legal norms contained in statutory regulations were interpreted using grammatical interpretation to examine the ordinary meaning of legal provisions, systematic interpretation to understand the relationship between provisions within the broader healthcare legal framework, and

teleological interpretation to identify the legislative objectives underlying the regulation of informed consent. Furthermore, the study employed thematic analysis to categorize legal doctrines and scholarly opinions concerning informed consent and criminal liability. The findings from these categories were then synthesized through normative legal analysis to evaluate the consistency between statutory provisions, legal doctrines, and theoretical principles.

Conclusions were drawn using a deductive legal reasoning model, beginning with general legal principles concerning legal protection, patient autonomy, justification defenses (*rechtvaardigingsgronden*), and criminal liability, and subsequently applying these principles to the specific issue of informed consent in healthcare practice. Through this process, the study formulates a juridical understanding of how informed consent functions as a mechanism for ensuring legal certainty, protecting medical personnel, and safeguarding patient rights under Indonesian health law.

3. Results

3.1. Informed Consent as a Fundamental Legal Instrument

The mechanism of informed consent is a formal, imperative instrument in the healthcare system before medical personnel execute clinical interventions on patients (Muhammad & Cut, 2024). This procedure is rooted in medical ethics fundamentals, establishing that every patient has a constitutional right to understand the urgency of their pathological condition, the significance of procedural risks, and therapeutic alternatives prior to giving consent (Arthanti, 2025). The existence of informed consent must not be reduced to a mere administrative formality on paper; rather, it must be viewed as a communication dialectic demanding information transparency and conscious cognitive understanding from the patient. This transformation reflects the principle of individual autonomy in the medical personnel-patient relationship ecosystem, holding legal binding power within the national health regulatory system (Mariyani, 2020).

The legality of a medical intervention is directly proportional to the validity of the informed consent obtained. In the national legal framework, obtaining informed consent constitutes an absolute obligation for medical personnel arising from professional standards, ethical principles, and statutory mandates. This legal construction refers to the principles contained in the Indonesian Civil Code, particularly Article 1320 concerning the validity requirements of an agreement, as well as various sectoral regulations in the healthcare system. In this context, informed consent functions not merely as an administrative requirement but as a legal instrument ensuring that patients consciously understand and approve the medical actions to be performed. The absence of valid informed consent may transform a medical procedure into an unlawful act that potentially gives rise to civil liability, administrative sanctions, or even criminal responsibility for healthcare professionals (Tambunan et al., 2025).

Although the concept of informed consent has been extensively discussed in legal and medical literature, its practical implementation remains constrained by various sectoral disparities. One of the principal obstacles is the literacy and communication gap between medical personnel and patients, particularly regarding the explanation of technical medical terminology and procedural risks (Irawati et al., 2020). Many patients still experience difficulties in fully understanding complex medical information, especially when explanations are delivered using highly technical language. This communication barrier ultimately weakens the effectiveness of information exchange, which is an essential prerequisite for valid consent. Consequently, consent provided under an inadequate understanding may be categorized as defective consent, thereby reducing its juridical validity as a legal protection instrument for medical personnel.

3.2. Legal Protection and the Elimination of Criminal Liability

The existence of informed consent in health criminal law is not merely an administrative requirement but holds a fundamental position as a reason for criminal exemption (*strafuitsluitingsgronden*). Invasive medical procedures often fulfill the objective elements of offenses against bodily integrity, such as maltreatment, because they involve physical intervention on a patient's body. However, their unlawfulness (*wederrechtelijkheid*) is eliminated through the patient's valid consent, which constitutes a recognized justification (*rechtvaardigingsgrond*) in criminal law. This doctrine is closely associated with the principle of individual autonomy and the concept of *toestemming van de benadeelde* (consent of the injured party), whereby an act affecting a legally protected interest may lose its unlawful character when valid consent has been granted by the rights holder. Accordingly, informed consent functions not only as a procedural safeguard but also as a juridical mechanism that legitimizes medical actions performed within professional standards and based on the patient's autonomous decision (Sastrani, 2025).

Under Law Number 17 of 2023 concerning Health, the position of informed consent is revitalized as a primary legal safeguard for medical personnel. Article 293 establishes cumulative parameters regarding the information that must be communicated, including diagnosis, medical procedures, risks, complications, alternatives, and prognosis. When these requirements are fulfilled, the resulting consent strengthens the legality of medical interventions and reduces the potential for criminal liability arising solely from inherent medical risks. From a criminal law perspective, it is important to distinguish between *wederrechtelijkheid* (unlawfulness) and *schuld* (culpability or fault). Valid informed consent primarily operates to eliminate the unlawful nature of a medical intervention because the patient has voluntarily authorized the action. By contrast, *schuld* concerns the conduct of the medical professional, particularly whether the procedure was performed negligently, recklessly, or contrary to professional standards. Therefore, informed consent may remove the element of unlawfulness, but it does not automatically eliminate fault if the healthcare provider commits professional negligence. Nevertheless, where risks have been adequately disclosed and voluntarily accepted by the patient, the principle of *volenti non fit iniuria* reinforces legal certainty by recognizing that adverse outcomes arising from accepted medical risks do not automatically constitute criminal wrongdoing (Harahap & Ma, 2025).

However, the efficacy of informed consent as a justification depends heavily on the integrity, completeness, and accuracy of the information provided to the patient (Nakagawa et al., 2024). If the information is partial, inaccurate, or misleading, the resulting consent may be categorized as vitiated consent and therefore lacks legal validity. In criminal law, defective consent cannot eliminate the unlawful character of a medical intervention because the patient's decision is not based on a genuine understanding. Moreover, informed consent does not provide legal protection where consent is obtained through coercion, fraud, or material misrepresentation, where the patient lacks legal competence to consent, where the medical procedure substantially exceeds the scope of the granted consent, or where the healthcare provider acts with gross negligence or in violation of professional standards. Under such circumstances, medical personnel may still incur civil, administrative, or criminal liability despite the existence of a signed consent form, as legal protection arises not from the document itself but from the validity of the consent process and compliance with professional obligations (Carstens, 2024).

3.3. Informed Consent in the Era of Digitalization and High-Risk Procedures

In the digitalization era, the evidentiary power of informed consent also acquires a new dimension through electronic documentation validation. The integration of health information systems in documenting the information provision process

strengthens the bargaining position of medical personnel in court as accountable evidence (Gustina et al., 2022). Electronic medical records and digital consent forms provide a more systematic and traceable mechanism for recording communication between healthcare professionals and patients. This development not only improves administrative efficiency in healthcare services but also enhances legal certainty by ensuring that every stage of information disclosure and patient approval is properly documented.

The use of digital documentation also minimizes the potential for disputes regarding whether information has been adequately conveyed to patients. Through electronic systems, hospitals and healthcare institutions are able to maintain more accurate records concerning the explanation of diagnoses, procedures, risks, alternatives, and patient approvals. Consequently, informed consent evolves into a stronger evidentiary instrument with higher probative value in litigation processes. In the context of criminal and civil disputes, electronically documented consent may function as supporting evidence demonstrating that medical personnel have fulfilled their professional and legal obligations in accordance with applicable healthcare regulations (Naurah, 2025).

The significance of informed consent becomes particularly crucial in high-risk medical procedures (Brazier & Cave, 2016). In complex interventions such as neurosurgery, organ transplantation, or emergency surgical procedures, medical consent becomes the primary legal instrument capable of transforming potential criminal liability into an acceptable medical risk. Through the principles of legality and patient autonomy, the state recognizes that risky medical actions remain legally justified as long as they are carried out based on transparent communication, professional standards, and voluntary patient approval. In this regard, informed consent serves not only as legal protection for medical personnel but also as a balancing mechanism between patient rights and the necessity of advancing healthcare services without criminalizing the medical profession.

4. Conclusion

This study concludes that informed consent constitutes a fundamental legal instrument in ensuring the legality of medical procedures and functioning as a basis for eliminating criminal liability for medical personnel within the Indonesian healthcare system. The transformation introduced through Law Number 17 of 2023 concerning Health strengthens the juridical position of informed consent as a preventive mechanism that guarantees legal certainty while maintaining patient autonomy through transparent and accountable communication. In criminal law, valid informed consent may operate as a justification defense by eliminating the unlawful nature of medical actions when patients have consciously accepted foreseeable medical risks. Consequently, informed consent also serves to distinguish unavoidable medical risks from criminal malpractice arising from negligence.

The implications of this study emphasize the importance of strengthening therapeutic communication, standardizing information disclosure procedures, and optimizing digital health documentation systems to enhance the evidentiary value of informed consent in medical disputes. Healthcare institutions and policymakers are encouraged to formulate more comprehensive operational standards to ensure uniform implementation of informed consent across healthcare services in Indonesia. In addition, the findings support the need for legal literacy improvement among both medical personnel and patients to minimize disputes caused by misunderstandings in medical communication.

However, this study is limited by its normative juridical approach, which relies primarily on secondary legal materials without incorporating empirical field data regarding the practical implementation of informed consent in hospitals or healthcare institutions. Therefore, future research is recommended to employ

empirical or socio-legal approaches involving healthcare professionals, patients, and legal practitioners to evaluate the effectiveness of informed consent practices and identify practical obstacles in the enforcement of legal protection for medical personnel in Indonesia.

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The data that support the findings of this study are available from the corresponding author upon reasonable request.