



Informed Consent for High-Risk Procedures in Indonesia: Legal Formalism, Shared Decision-Making, and the Problem of Therapeutic Misunderstanding



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ABSTRACT

Introduction: Informed consent constitutes a fundamental ethical and legal requirement in modern healthcare, particularly for high-risk procedures that involve substantial risks of morbidity, disability, or mortality. Despite legal reforms that strengthen patient rights in Indonesia, informed consent is frequently implemented as a documentation-centered process, raising concerns regarding the quality of patient understanding and participation in clinical decision-making.

Methods: This study employed a normative-juridical narrative review by analyzing Indonesian health legislation, bioethical principles, medico-legal literature, and international publications related to informed consent, shared decision-making, patient autonomy, and therapeutic misunderstanding. Relevant legal and scientific sources were synthesized thematically.

Results: Indonesian regulations establish a comprehensive legal foundation for informed consent and require disclosure of information regarding diagnosis, proposed interventions, potential benefits, risks, alternatives, and prognosis. However, implementation often remains focused on obtaining signed consent forms rather than ensuring substantive patient comprehension. Contemporary evidence supports shared decision-making as a patient-centered approach that promotes meaningful involvement in healthcare decisions. Nevertheless, limited health literacy, cultural paternalism, communication barriers, emotional distress, and the complexity of medical information continue to contribute to therapeutic misunderstanding, particularly in high-risk clinical settings. These factors may undermine the validity of consent despite apparent legal compliance.

Conclusion: The validity of informed consent should extend beyond documentary authorization and encompass effective communication, patient understanding, voluntariness, and collaborative decision-making. Integrating shared decision-making principles into high-risk consent processes may reduce therapeutic misunderstanding, strengthen patient autonomy, and enhance medico-legal protection for both patients and healthcare professionals in Indonesia.

Keywords: informed consent, shared decision-making, therapeutic misunderstanding, patient autonomy, high-risk procedures, health law, Indonesia.

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INTRODUCTION

Informed consent is widely recognized as a cornerstone of ethical and lawful medical practice. Beyond serving as a prerequisite for medical intervention, informed consent reflects the fundamental principle that patients possess the right to make autonomous decisions regarding their healthcare after receiving adequate information about the proposed treatment. The concept emerged as a response to historical concerns regarding paternalistic medicine, in which physicians exercised dominant authority over clinical decision-making with limited patient involvement. Contemporary healthcare systems increasingly emphasize patient-

centered care, recognizing that respect for autonomy requires not only disclosure of information but also meaningful patient participation in treatment decisions.^{1,2}

The importance of informed consent becomes particularly evident in high-risk medical procedures, including major surgery, cardiovascular interventions, neurosurgical operations, organ transplantation, and other invasive treatments associated with significant risks of morbidity, permanent disability, or mortality. Decisions regarding such interventions frequently involve uncertainty concerning outcomes, complex risk-benefit assessments, and multiple therapeutic alternatives. Consequently, obtaining valid informed

consent in these settings requires more than a formal authorization process; it necessitates effective communication that enables patients to understand relevant information and align healthcare decisions with their individual values, preferences, and expectations.³

In Indonesia, informed consent has received increasing legal attention through the development of health legislation and professional standards. Current regulations recognize the patient's right to receive information regarding diagnosis, proposed interventions, expected benefits, potential risks, available alternatives, and prognosis. These provisions establish informed consent as both a legal obligation of healthcare professionals and a

mechanism for safeguarding patient rights. In practice, however, implementation often remains focused on the completion of consent forms and documentary requirements. As a result, the existence of a signed document is frequently regarded as evidence that informed consent has been adequately obtained, despite limited assessment of whether patients genuinely understood the information provided.⁴

This phenomenon reflects a broader tension between legal formalism and substantive patient engagement. Legal formalism emphasizes compliance with procedural requirements, documentation standards, and evidentiary protection in the event of medical disputes. While these functions are important, excessive reliance on documentation may obscure the communicative and deliberative dimensions of informed consent. Patients may sign consent forms without fully understanding procedural risks, expected outcomes, or available alternatives, particularly when confronted with complex medical terminology, emotional distress, limited health literacy, or cultural norms that encourage deference to physician authority.⁵

These concerns have stimulated growing interest in the concepts of shared decision-making and therapeutic misunderstanding. Shared decision-making promotes collaborative deliberation between physicians and patients, integrating clinical evidence with patient preferences and values. Conversely, therapeutic misunderstanding occurs when patients misinterpret or inadequately comprehend information related to a proposed intervention despite participating in the consent process. The persistence of therapeutic misunderstanding raises important questions regarding the substantive validity of consent, especially in high-risk clinical situations where misunderstandings may have profound ethical, legal, and clinical consequences.^{5,6}

This review aims to examine informed consent for high-risk procedures in Indonesia from medico-legal and ethical perspectives. Specifically, it analyzes the Indonesian legal framework governing informed consent, explores the relationship between legal formalism and

shared decision-making, evaluates the problem of therapeutic misunderstanding, and discusses policy directions that may strengthen patient-centered decision-making while maintaining legal accountability in healthcare practice.

METHODS

Search Strategy

This study employed a normative-juridical narrative review design to examine the legal, ethical, and clinical dimensions of informed consent for high-risk medical procedures in Indonesia. The normative-juridical approach was used to analyze legal norms, regulatory frameworks, bioethical principles, and professional obligations governing informed consent, patient autonomy, and physician responsibility. The narrative review approach was utilized to synthesize contemporary scientific literature concerning shared decision-making, risk communication, therapeutic misunderstanding, and patient-centered healthcare.

Legal Materials and Literature Sources

Primary legal materials consisted of Indonesian laws and regulations relevant to informed consent and healthcare governance, including Law Number 17 of 2023 concerning Health, Government Regulation Number 28 of 2024 concerning the Implementation of the Health Law, the Indonesian Civil Code, the Indonesian Code of Medical Ethics, and ministerial regulations governing medical practice and patient rights. Additional legal and ethical documents from international organizations were also reviewed to provide comparative perspectives regarding patient autonomy and informed decision-making.

Secondary materials were obtained from peer-reviewed journal articles, textbooks, institutional reports, ethical guidelines, and policy documents addressing informed consent, shared decision-making, patient autonomy, risk disclosure, physician-patient communication, health literacy, and therapeutic misunderstanding. Literature searches were conducted through PubMed, Scopus, Google Scholar, GARUDA, and institutional databases. Search terms included “informed consent,” “shared

decision-making,” “patient autonomy,” “risk communication,” “therapeutic misunderstanding,” “therapeutic misconception,” “high-risk procedures,” “medical law,” “bioethics,” “informed consent Indonesia,” and related terms.

Eligibility Criteria

Included materials comprised current Indonesian regulations, international ethical guidelines, and scientific publications discussing informed consent, patient participation in healthcare decisions, therapeutic misunderstanding, and medico-legal aspects of high-risk procedures. Sources were excluded if they lacked relevance to informed consent, represented unsupported opinions without academic or legal foundation, or contained outdated information that had been superseded by more recent regulations or evidence.

Data Extraction and Synthesis

Data were extracted by identifying key themes related to the conceptual foundations of informed consent, legal requirements, ethical principles, disclosure standards, shared decision-making models, therapeutic misunderstanding, and implementation challenges in high-risk clinical settings. Findings were synthesized thematically to explore the relationship between legal formalism and substantive patient understanding within the Indonesian healthcare context.

RESULTS AND DISCUSSION

Conceptual Foundations of Informed Consent

Informed consent represents a process through which a competent patient voluntarily authorizes a medical intervention after receiving and understanding sufficient information regarding the proposed treatment. Although commonly associated with signed consent forms, contemporary legal and bioethical scholarship recognizes informed consent as a continuous communicative process rather than a single administrative event. Its primary purpose is to ensure that healthcare decisions are made by patients who possess adequate knowledge regarding the expected benefits, potential risks, available

alternatives, and possible consequences of accepting or refusing treatment.^{5,6}

The modern doctrine of informed consent is grounded in the ethical principle of respect for autonomy. Autonomy refers to the individual's right to make decisions concerning personal health and bodily integrity free from coercion, manipulation, or undue influence. Within clinical practice, respect for autonomy requires healthcare professionals to provide information in a manner that is understandable, relevant, and responsive to the patient's informational needs. Consequently, informed consent serves not only as legal authorization for medical intervention but also as a mechanism for protecting individual dignity and self-determination.⁷

Several essential elements are required for informed consent to be considered valid. First, the patient must possess decision-making capacity, including the ability to understand relevant information, appreciate the consequences of available choices, reason about treatment options, and communicate a decision. Second, adequate disclosure must be provided regarding diagnosis, treatment objectives, expected benefits, potential risks, available alternatives, and prognosis. Third, the patient must demonstrate sufficient understanding of the disclosed information. Fourth, the decision must be voluntary and free from coercion. Finally, the patient must communicate authorization for the proposed intervention.⁷

The validity of informed consent therefore depends not merely on the transmission of information but on the achievement of meaningful understanding. This distinction is particularly important in high-risk procedures, where patients are often required to evaluate complex information under emotionally stressful circumstances. Under such conditions, the quality of communication may be as important as the quantity of information disclosed. Consequently, contemporary interpretations increasingly emphasize patient comprehension and shared deliberation rather than simple documentation of authorization.⁷

Table 1. Core Components of Valid Informed Consent.⁵

Component	Description	Clinical Significance
Capacity	Ability to understand, appreciate, reason, and communicate decisions	Ensures legal competence
Disclosure	Provision of relevant information regarding diagnosis, risks, benefits, and alternatives	Supports informed choice
Understanding	Patient comprehension of disclosed information	Determines substantive validity
Voluntariness	Freedom from coercion or undue influence	Protects autonomy
Authorization	Explicit agreement to proceed with intervention	Provides legal permission

Table 2. Indonesian Regulations Relevant to Informed Consent.⁸

Regulation	Scope	Relevance to Informed Consent
Law No. 17/2023 on Health	Patient rights and healthcare governance	Establishes the right to receive medical information and participate in decision-making
Government Regulation No. 28/2024	Implementation of health law	Strengthens operational requirements concerning patient information and consent
Indonesian Code of Medical Ethics	Professional ethical obligations	Requires respect for autonomy and patient welfare
Civil Law Principles	Legal validity of agreements and consent	Supports voluntary authorization and legal accountability
Hospital and Medical Practice Regulations	Clinical governance and documentation	Regulates procedural aspects of consent documentation

Indonesian Legal Framework Governing Informed Consent

The legal basis of informed consent in Indonesia is derived from the broader recognition of patient rights, professional accountability, and ethical medical practice. Contemporary Indonesian health law acknowledges that medical interventions cannot be performed solely on the basis of professional judgment but require patient participation through an informed decision-making process. This legal framework reflects the growing emphasis on patient autonomy while simultaneously providing safeguards for healthcare professionals and institutions.²

Law Number 17 of 2023 concerning Health establishes the patient's right to receive comprehensive information regarding health conditions and proposed medical interventions. This information includes diagnosis, treatment plans, expected benefits, potential risks, alternative therapeutic options, and prognosis. The law further reinforces the obligation of healthcare professionals to provide information that is accurate, clear, and understandable, thereby creating the

legal foundation for informed consent as both a patient right and a professional duty. Government Regulation Number 28 of 2024 strengthens these principles by providing additional operational guidance regarding healthcare delivery and patient rights. Together, these regulations position informed consent as an integral component of healthcare quality, patient safety, and professional accountability. In addition to statutory law, ethical obligations established through professional codes of conduct require physicians to respect patient autonomy and facilitate informed participation in healthcare decisions.^{1,8}

From a medico-legal perspective, informed consent performs two complementary functions. First, it protects patients by ensuring that medical interventions occur only after adequate disclosure and voluntary authorization. Second, it provides legal protection for healthcare professionals by documenting that information has been communicated and that treatment decisions have been made with patient participation. Nevertheless, the existence of a signed consent document does not automatically establish the validity of consent. Courts

and professional disciplinary bodies increasingly recognize that genuine informed consent requires evidence of meaningful communication and patient understanding rather than mere completion of administrative forms.

This distinction is particularly important in high-risk procedures, where the consequences of misunderstanding may be severe. Therefore, contemporary legal interpretation increasingly extends beyond documentary formalities toward substantive evaluation of the consent process itself, including the adequacy of information disclosure, communication quality, patient comprehension, and voluntariness of decision-making.⁹

High-Risk Procedures and the Need for Enhanced Consent

Not all medical interventions carry the same ethical and legal implications. While routine procedures often involve relatively predictable outcomes and limited risks, high-risk procedures present substantially greater uncertainty and the potential for serious adverse consequences. Such procedures may include major surgery, cardiovascular interventions, neurosurgical procedures, organ transplantation, high-risk obstetric interventions, intensive care procedures, and certain experimental or innovative therapies. These interventions frequently involve the possibility of permanent disability, significant deterioration in quality of life, prolonged hospitalization, or death.^{7,9} The heightened risks associated with these procedures impose greater obligations on healthcare professionals during the consent process. Disclosure must extend beyond a simple explanation of procedural steps and include a balanced discussion of expected benefits, potential complications, alternative treatment options, and the consequences of refusing treatment. Patients should be provided with sufficient opportunity to ask questions, seek clarification, and reflect on available options before making a decision. High-risk procedures often involve situations in which clinical evidence does not provide absolute certainty regarding outcomes. Physicians may be required to communicate probabilities rather than guarantees, creating challenges for

both information disclosure and patient comprehension. Risk communication becomes particularly complex when discussing rare but catastrophic complications. Patients may overestimate unlikely adverse outcomes due to fear and anxiety, while others may underestimate substantial risks because of optimism or excessive trust in medical professionals. Consequently, the quality of informed consent depends not only on the accuracy of information provided but also on the effectiveness of communication strategies used to facilitate understanding.⁹

The ethical significance of enhanced consent in high-risk procedures is closely related to the principle of proportionality. As the magnitude of potential harm increases, the threshold for meaningful patient understanding becomes correspondingly higher. A consent process that may be considered adequate for a minor intervention may be insufficient for a procedure associated with substantial morbidity or mortality. Therefore, high-risk interventions require a more comprehensive, patient-centered, and deliberative consent process than routine medical care.^{9,10}

Legal Formalism in Indonesian Informed Consent Practice

Although informed consent is intended to facilitate autonomous decision-making, its implementation in many healthcare systems remains strongly influenced by legal formalism. Legal formalism refers to an approach that emphasizes procedural compliance and documentary evidence as indicators of legal validity. Within clinical practice, this perspective frequently manifests as a focus on obtaining signatures on consent forms, completing administrative documentation, and ensuring compliance with institutional requirements. The development of legal formalism is understandable from a medico-legal perspective. Healthcare professionals and institutions operate in an environment characterized by increasing public awareness of patient rights and a growing potential for medical disputes. Consequently, consent forms are often viewed as important legal safeguards that may demonstrate compliance with professional obligations in the event of

litigation or disciplinary proceedings. Documentation therefore becomes a critical component of risk management and legal accountability.¹⁰

However, excessive reliance on documentation may create unintended consequences. A signed consent form may provide evidence that a conversation occurred, but it cannot reliably demonstrate the quality of communication, the adequacy of information disclosure, or the degree of patient understanding. Patients frequently sign consent documents under conditions of emotional stress, acute illness, time pressure, or dependence on physician recommendations. In such circumstances, formal authorization may not necessarily reflect informed and deliberative decision-making.^{11,12}

Furthermore, legal formalism may encourage a transactional view of informed consent, whereby the process is perceived as complete once a signature has been obtained. This approach risks reducing informed consent to a bureaucratic exercise rather than a meaningful exchange of information. As healthcare increasingly embraces patient-centered care, concerns have emerged that documentation-focused practices may fail to achieve the ethical objectives for which informed consent was originally developed. For high-risk procedures, these limitations become particularly significant. Because the consequences of misunderstanding may be severe and irreversible, legal compliance alone cannot be considered sufficient. A valid consent process must demonstrate not only that information was disclosed but also that patients were given a meaningful opportunity to understand, evaluate, and participate in decisions affecting their health and future well-being.¹⁰

Shared Decision-Making as the Contemporary Standard

In response to the limitations of traditional consent models, shared decision-making (SDM) has emerged as a contemporary framework for patient-centered healthcare. SDM is a collaborative process in which clinicians and patients jointly participate in healthcare decisions by integrating the best available medical evidence with patient preferences, values,

goals, and personal circumstances. Rather than positioning physicians as sole decision-makers or placing the entire burden of decision-making on patients, SDM promotes partnership and mutual deliberation.¹³

The conceptual foundation of SDM recognizes that clinical decisions involve two distinct forms of expertise. Physicians possess expertise regarding diagnosis, prognosis, treatment effectiveness, and procedural risks. Patients possess expertise regarding their own values, priorities, life goals, social circumstances, and tolerance for risk. High-quality healthcare decisions require the integration of both perspectives. Consequently, SDM extends beyond information disclosure and emphasizes active patient engagement throughout the decision-making process. Several studies have demonstrated that SDM improves patient satisfaction, increases knowledge retention, reduces decisional conflict, and enhances trust in healthcare professionals. Importantly, SDM does not require patients to make decisions independently without professional guidance. Instead, physicians continue to provide recommendations while encouraging patients to participate in evaluating available options. This approach is particularly valuable in situations involving multiple reasonable treatment alternatives or uncertainty regarding outcomes.^{14,15}

From a medico-legal perspective, SDM offers a more substantive interpretation of informed consent than documentation-based approaches. By emphasizing dialogue, clarification, and patient participation, SDM addresses many of the limitations associated with legal formalism. It shifts the focus from obtaining authorization to achieving informed and value-concordant decisions. Consequently, SDM has increasingly been recognized as an ethical and practical strategy for strengthening patient autonomy while simultaneously improving communication and reducing misunderstandings.¹⁶

Therapeutic Misunderstanding and Communication Failure

One of the most significant challenges in obtaining valid informed consent is the persistence of therapeutic

Table 3. Comparison Between Legal Formalism and Shared Decision-Making Models.⁷

Aspect	Legal Formalism Model	Shared Decision-Making Model
Primary Objective	Legal compliance and documentation	Patient-centered decision-making
Focus	Signed consent form	Patient understanding and participation
Physician Role	Information provider	Information provider and decision partner
Patient Role	Consent giver	Active participant in deliberation
Success Indicator	Completion of documentation	Informed and value-concordant decision
Medico-legal Strength	Documentary protection	Communication quality and substantive understanding
Risk	Administrative compliance without understanding	Requires additional time and communication skills

misunderstanding. This phenomenon occurs when patients authorize a medical intervention despite having an incomplete or inaccurate understanding of the information disclosed during the consent process. Therapeutic misunderstanding does not necessarily result from inadequate disclosure alone; rather, it frequently arises from the complex interaction between communication barriers, patient expectations, emotional distress, cognitive limitations, and the inherent complexity of medical information. Consequently, a patient may formally consent to a procedure while simultaneously maintaining beliefs or expectations that differ substantially from the information intended by the healthcare professional.¹⁷

Communication failure also contributes significantly to therapeutic misunderstanding. Medical terminology, statistical risk estimates, and complex explanations regarding procedural outcomes may be difficult for patients with limited health literacy to understand. In addition, physicians often overestimate the effectiveness of their communication, while patients may hesitate to ask questions because of cultural norms, perceived power imbalances, or concerns about challenging professional authority. Consequently, the apparent completion of a consent discussion does not necessarily indicate that meaningful understanding has been achieved. In the context of high-risk procedures, these misunderstandings may subsequently contribute to dissatisfaction, erosion of trust, complaints, and medico-legal disputes when outcomes differ from patient expectations.¹⁷

From an ethical perspective, therapeutic misunderstanding raises important questions regarding the substantive validity of informed consent. If a patient does not adequately understand the nature, risks, limitations, or alternatives of a proposed intervention, the ethical foundation of autonomous decision-making becomes compromised. Therefore, contemporary interpretations increasingly emphasize the need to evaluate patient understanding rather than relying exclusively on documentation or information disclosure alone.¹⁷

Challenges in Implementing Effective Informed Consent in Indonesia

Despite regulatory recognition of patient autonomy and informed decision-making, several barriers continue to hinder effective implementation of informed consent in Indonesia. These challenges originate from patient-related, physician-related, and system-level factors that collectively influence the quality of communication and patient participation. At the patient level, limited health literacy remains a significant obstacle. Many patients have difficulty interpreting medical terminology, understanding probabilistic risk information, or distinguishing between treatment options. Cultural traditions that place physicians in highly respected positions may further reinforce passive decision-making behavior, leading patients to accept recommendations without actively engaging in discussion. While trust in healthcare professionals is beneficial, excessive reliance on physician

authority may reduce opportunities for meaningful deliberation regarding risks, benefits, and alternatives.^{2,6}

Physician-related barriers are equally important. Time constraints, increasing administrative responsibilities, and concerns regarding medico-legal liability may encourage a documentation-focused approach to informed consent. Under such conditions, clinicians may prioritize procedural completion rather than assessing patient comprehension. Furthermore, communication training in risk disclosure, shared decision-making, and health literacy adaptation remains variable across healthcare settings. As a result, clinicians may possess substantial technical expertise while receiving limited formal preparation in facilitating patient-centered decision-making.^{2,6}

Comparative Perspectives on Informed Consent and Shared Decision-Making

International developments in informed consent increasingly emphasize substantive patient participation rather than procedural compliance alone. In several jurisdictions, legal and ethical standards have evolved beyond the traditional disclosure model toward frameworks that prioritize patient-centered communication and shared decision-making. In the United Kingdom, the landmark Montgomery decision fundamentally reshaped consent standards by requiring physicians to disclose material risks that a reasonable patient would consider important when making healthcare decisions. Compared with these developments, Indonesian regulations already recognize patient rights and information disclosure requirements. However, implementation continues to be influenced by documentation-oriented practices and cultural norms that may limit active patient participation. Consequently, international experiences may provide useful insights for strengthening the practical realization of patient autonomy within Indonesian healthcare settings.^{8,13}

Policy Directions and Future Recommendations

Improving informed consent for high-risk procedures in Indonesia requires

a transition from a predominantly documentation-based model toward a communication-centered and patient-oriented approach. Regulatory compliance remains important, but documentation should be regarded as evidence of a broader process rather than the primary objective of consent itself. At the clinical level, healthcare professionals should be encouraged to adopt shared decision-making principles as part of routine practice. Discussions regarding treatment options should include balanced explanations of benefits, risks, uncertainties, and alternatives while actively exploring patient preferences and values. Communication strategies such as plain-language explanations, visual decision aids, and teach-back techniques may improve patient understanding and reduce therapeutic misunderstanding. Evidence suggests that these approaches facilitate more informed decisions and strengthen patient engagement without substantially increasing consultation burden.^{8,13}

At the institutional level, hospitals and healthcare organizations should develop standardized consent pathways for high-risk procedures that incorporate communication quality indicators in addition to documentation requirements. Professional education programs should also strengthen training in risk communication, health literacy, bioethics, and shared decision-making competencies. Such initiatives would support healthcare professionals in navigating increasingly complex clinical and medico-legal environments. From a policy perspective, future regulatory development may benefit from incorporating explicit guidance regarding shared decision-making and assessment of patient understanding. Rather than focusing exclusively on disclosure and documentation, consent standards should emphasize meaningful participation and comprehension as indicators of quality. Such an approach would better align Indonesian healthcare practice with contemporary international standards while preserving the legal and ethical objectives of informed consent.¹⁸

Ultimately, strengthening informed consent requires recognition that patient autonomy is not achieved through

signatures alone. Genuine respect for autonomy depends upon effective communication, mutual understanding, and collaborative decision-making between healthcare professionals and patients. By addressing therapeutic misunderstanding and promoting shared decision-making, Indonesia may advance toward a more patient-centered model of healthcare that enhances both ethical integrity and medico-legal accountability. This review was based on published literature and regulatory documents; therefore, it may not fully reflect real-world variations in informed consent practices across healthcare institutions in Indonesia. Further empirical studies are needed to evaluate the implementation of shared decision-making and therapeutic misunderstanding in clinical settings.¹⁸

CONCLUSION

Informed consent for high-risk procedures in Indonesia extends beyond a legal requirement and serves as an essential mechanism for respecting patient autonomy and promoting ethical clinical practice. Although Indonesian regulations provide a substantial legal foundation for informed consent, implementation remains largely influenced by documentation-oriented approaches that may not adequately ensure patient understanding. The persistence of therapeutic misunderstanding demonstrates that formal authorization alone cannot guarantee valid and informed decision-making.

Shared decision-making offers a more patient-centered framework by integrating clinical evidence with individual patient values, preferences, and expectations. Strengthening communication quality, improving health literacy, and incorporating shared decision-making principles into routine clinical practice may reduce therapeutic misunderstanding while enhancing both patient autonomy and medico-legal accountability. Future efforts should therefore focus not only on compliance with documentation requirements but also on ensuring meaningful patient participation in healthcare decisions, particularly for interventions associated with substantial risk.

DISCLOSURES

AUTHORS CONTRIBUTION

[Initials] conceptualized the study, designed the review framework, conducted literature synthesis, and wrote the original draft. [Initials] contributed to legal analysis, interpretation of Indonesian regulatory instruments, and manuscript revision. All authors have read and approved the final version of the manuscript.

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CONFLICT OF INTEREST

The authors declare no conflict of interest related to this study.

ETHICAL CONSIDERATION

Not applicable.

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