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Use Of Standard Clauses in Transactions Therapeutics Based on Regulation Theory

Carwan[1], Sari Indah Lestari[2]
Legal Studies, Faculty of Law, Universitas Pakuan Bogor, Indonesia[1,2]
Email: carwansp@gmail.com[1], sariindahlestari@gmail.com[2]

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ABSTRACT

The standard informed consent clause is prepared and formed by one of the parties to make it easier for doctors and patients to create a therapeutic agreement. One of the parties designed and developed this standard clause to make it easier for doctors and patients to form a therapeutic contract. However, in practice, it is found that the application of standard clauses prepared in advance by hospitals or doctors is only concerned with signatures and has an impact of dissatisfaction that is detrimental to patients. The research method used is juridical-normative. The results showed that based on the theory of legislation, normatively, the standard clause does not violate the principle of freedom of contract because the standard informed consent clause in the Therapeutic Transaction is a form of the initiative of doctors and hospitals as parties who have more expertise to form the main guidelines for doctors and patients in carrying out health services. In Decision Number 63/Pdt.G/2021/PN Kpn, the use of standardized informed consent clauses in therapeutic agreements provides repressive legal protection in the trial and has a positive influence, namely strengthening informed consent as vital and valid evidence in the problem because it has guided whether medical actions are carried out by the agreed actions, SP, SOP, and patient needs.

INTRODUCTION

Approval of medical action, often called informed consent, is the basis for the legal relationship and engagement between patients and doctors or health workers in therapeutic transactions. As science and technology develop in medical practice, medical or health law development increases as a guide for doctors, health workers, and patients in therapeutic transactions.

According to the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Procedures (Permenkes Number 290 of 2008), the definition of approval for medical procedures or informed consent is the consent given by the patient or the closest family after receiving a complete explanation regarding the medical or dental procedures that will be carried out on the patient (Mayasari, 2017). Therefore, it is necessary to thoroughly explain the partnership between doctors and patients as subjects with equal status. Each has rights and obligations that must be fulfilled (Mustajab, 2013).

The relationship between doctors and patients regarding these rights and obligations is outlined in informed consent. In health law, there are 2 (two) basic human rights, namely basic social rights and primary individual rights (Basuki, 2020). One of the basic social rights that stands out is the right to health services or healthcare, which means that every human being has the right to access a standard of living

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adequate for their health and well-being (Dewi & Ernawati, 2023). Then, the basic individual right that stands out is the right of self-determination. These basic rights are regulated in Article 1 and Article 7 of the International Covenant on Civil and Political Rights (ICCPR) (Otenyo, 2023). The contents of this article then became the basis and urgency of its formation of informed consent as a fulfillment of legal certainty and legal protection (Sugiarti et al., 2020).

The right of self-determination also becomes the basis for forming other individual fundamentals that serve as the foundation of the relationship between doctors and patients, as stated in informed consent, namely the right to determine one's fate and the right to information. In informed consent, two fundamental individual rights have been mentioned above.

Consent to medical procedures relies on the patient's right to information, which means that patients who are adults and of sound mind have the right to know medical information, whether requested or unsolicited, and health workers, namely doctors, are obliged to convey this information (Ratman, 2013). Related things that must be informed are the diagnosis, the therapy to be carried out and the procedure, the doctor's experience in carrying out the process, the risks that may occur both physically and behaviorally, and the benefits or prognosis (Busro, 2018).

Information related to therapeutic transactions is mandatory because it can be used as a basis for the patient's approval or refusal of medical treatment and as a protection for the patient's right to determine themselves (Grin et al., 2020; Zamir et al., n.d.). Then, there is also the patient's right to decide for themselves that is, after knowing the relevant information containing the procedure, diagnosis, prognosis, and all information related to the therapy to be carried out, the patient can determine that he refuses or agrees to the action without coercion from other people.

If the patient has agreed, the therapy or medical action can be carried out per the previously agreed-upon explanation, information, and procedures. Still, if the patient refuses, even though the treatment must be carried out for the patient's recovery, the doctor must respect the patient's choice and refusal of medical action. This is called informed refusal. Consent from the patient for the medical activity to be carried out can be given verbally or in writing. Forms of support can be divided into 2 (two), namely, consent that is clearly stated (express consent) and consent deemed to be given (implied or tacit approval) (Guwandi, 2008).

2 (two) forms of consent are clearly stated (express consent), namely verbal consent, in Article 3 paragraph (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions states that the medicines that do not involve high risks can be given with verbal consent. Then, there is a written agreement written and signed on a particular form, which contains a statement that the patient agrees to the high-risk medical action that will be carried out after receiving specific explanations and information from the doctor or health worker regarding the medical activity (Wan et al., 2023).

Of all the forms of consent that have been explained, it can be said that informed consent has become a particular concern in the relationship between doctors and patients in carrying out therapeutic transactions because it is expected that informed consent can be used as evidence of the existence of a legal relationship between a doctor and a patient, can provide initial guidance regarding the contents of the agreement for medical action that the patient agreed to with the doctor, can be used as a measuring tool for whether or not there are elements of legal violations, disciplinary violations or ethical violations of medical practice, can be used as a foundation for medical action doctors comply with professional standards, and can provide protection for both parties from medical risk disputes that arise. When viewed from a civil aspect, the provisions regarding engagement and civil liability in therapeutic transactions are closely related to implementing informed consent (Chaeria et al., 2020).

In forming informed consent, patients and doctors must comply with Article 1320 of the Civil Code, which discusses the 4 (four) conditions for a valid agreement, namely the existence of a contract between the parties wishing to bind themselves, the ability of the parties to form an agreement, the presence of a sure thing being agreed upon, and the existence of a reason that halal (Subekti, 2001). These four conditions apply in forming informed consent in therapeutic transactions and can be canceled or deemed to be the absence of an agreement. In civil law, there are 2 (two) forms of contract, namely: Result in verboten, engagements that require achievement or are based on work results, and effort commitment, namely a meeting based on maximum effort (Marzuki, 2013).

A therapeutic contract or transaction is included in an effort commitment where the medical action does not require results. Still, the movement must be by standard operational procedures and patient needs. It can also be in efforts to treat or prevent disease and maintain or restore health that does not require results, but the action must comply with health service standards. Even though its deep effort commitment has underlined that this engagement is an engagement based on activities, in this case, the doctor or health worker, to carry out maximum efforts in carrying out medical procedures, the patient can still ask for legal responsibility if there is a loss that arises because the doctor or health worker did not carry out medical procedures according to the instructions. Doctors who have been approved need to provide comprehensive information and could also, due to negligence, cause harm to patients or malpractice. In filing a lawsuit related to a medical dispute, the patient can also point to a law for informed consent as a basis and evidence of which trial reported consent. This can prove the existence of a relationship containing the rights and obligations of both the patient and the doctor in carrying out the approved therapeutic transaction.

In its development, there has been regulation and application of standard clauses in drafting informed consent (Biane et al., 2019). This standard clause is prepared and formed by one of the parties to make it easier for doctors and patients to create a therapeutic agreement ((SSHJ) & 2019, 2019). This standard clause is prepared and developed by one of the parties to make it easier for doctors and patients to create a therapeutic agreement. However, in practice, it is found that by implementing standard clauses prepared in advance by hospitals or doctors, they only prioritize signatures and have dissatisfaction impacts that are detrimental to patients (Walzer & Miltimore, 1993). With that, further analysis and adjustments should be carried out so that the standard clauses stated in informed consent can explain the legal relationships that arise regarding the rights and obligations that patients, doctors, or health workers have in therapeutic transactions. This is an urgent matter of informed consent. It is hoped that it can provide a form of legal certainty and legal protection for doctors, health workers, and patients and be used as legal and binding evidence in disputes or cases of permitted deviation from medical practice.

METHODS

The type of method used in this research is a normative legal research method. The normative legal research method is finding legal rules, principles, and doctrines to answer the legal problems Field faces (Fajar & Achmad, 2017). The approach in this research that the author will use is the statutory and case approaches. The statutory process examines all laws and other regulations related to handling the legal issue (Marzuki, 2013). Meanwhile, the case approach is an approach that uses reason for falling, namely the legal reasons used by the judge to arrive at his decision, and this shows that legal science is a prescriptive science, not descriptive.

In this research, the author uses secondary data. This type of secondary data is obtained from a literature review, various literature, or library material related to problems or research materials, often called legal materials. In this normative legal research method, there are 2 (two) types of legal materials used by the author, including the following: Primary Legal Materials, namely materials that constitute

statutory provisions, and Secondary legal materials, namely legal materials that can explain primary legal materials., such as draft laws, research results, work from legal circles, and so on.

RESULTS

A. Use of Standard Clauses in Therapeutic Transactions Based on Legislative Theory

When looking at usage standard clauses In America, there are no specific regulations regarding the use of standard clauses in preparation of informed consent. However, experts and government agencies in Canada, more precisely the Ministry of Health and Social Services in Quebec, have formed standard clauses that can be used in informed consent forms. The standard provisions that have been formed are then outlined in a document, which will guide doctors, health workers, and health service facilities in preparing informed consent. In this document, experts set out standard clauses that can be used along with a detailed understanding of the forms of protection that can be provided and the legal consequences if these clauses are written. Experts and agencies are also trying to develop and update the document regularly to make preparing and approving standard clauses for informed consent more effective and efficient (Gerst et al., 2022).

When analyzing the use of standard clauses in the composition of informed consent In Indonesia, it can be said that there are also guidance documents related to the preparation *of* informed consent. This document is a drafting guidance document for informed consent. However, this document needs to detail the standard clauses like the documents used by Canada.

Based on the Medical Practice Law, this law provides attribution to the Indonesian Medical Council (KKI) as an organ that has the function of evaluator and supervisor of doctors and dentists in medical practice. This attribution gives KKI the right to carry out guidance, one of which is issuing regulations related to the implementation of medical practice. In carrying out medical practice, doctors must pay attention to the 4 (four) pillars of medical ethics, namely (Jahn, 2011):

1. **Beneficence**

   Principle beneficence: It is a doctor's moral obligation to act in the interests of others. The obligation is divided into 2 (two): the obligation to provide benefits and the commitment to balance benefits, risks, and dangers. In carrying out any form of medical practice, a doctor is obliged to estimate whether the medical action to be carried out will bring more benefits to the patient, considering that there is a possible risk of complications. Apart from that, doctors must also continuously develop and maintain their skills and knowledge, attend training, and consider the individual circumstances of all patients.

2. **Non-Maleficence**

   Principle non-maleficence states that a doctor is obligated not to harm other people. This is closely related to the first thing is not to break or, as it is commonly known, first do not harm. As well as goodwill, the doctor must consider whether the action to be taken is commensurate with the possible risks or losses that will arise. Doctors cannot simply carry out activities without consideration because medical procedures or, more precisely, invasive procedures can cause suffering and even death in the patient. Therefore, before recommending or carrying out medical action, the doctor must estimate the possibilities that will occur and ensure that the move will provide benefits and prevent harm that will arise.

3. **Justice**

   Principle justice or justice requires doctors to distribute all forms of benefits, risks, costs, and resources fairly. Implementation of this principle requires doctors to provide health services to

everyone who needs them regardless of age, gender, etc., and to carry out every medical action according to the patient's needs.

4. Autonomy

Principle autonomy explains the doctor's respect for patient autonomy as a party who can act deliberately, with understanding, and without controlling influences that would reduce free and voluntary actions. This principle is the basis for implementing medical action approval in therapeutic transactions.

To ensure that the principles are implemented with autonomy, KKI also prepared a manual for approval of medical procedures as a guidance document for doctors in carrying out approval for medical procedures. This manual generally explains and details provisions such as (1) Implementation of approval for medical procedures; (2) The party who can give consent; (3) Providing information; (4) Implementation of rejection of inspection/action); (5) Format for providing information; and (6) Form of approval for medical procedures. Let us look at the format for approval for medical procedures. The KKI has prepared standard clauses that must be included in providing information and the implementation of approval for medical procedures and has required every hospital to be guided by this example format. The following is an example of the minimum standard design for approval for medical procedures that the KKI has prepared:

PEMBERIAN INFORMASI

Dokter Pelaksana Tindakan			
Pemberi informasi			
Penerima Informasi / pemberi persetujuan *			
	JENIS INFORMASI	ISI INFORMASI	TANDA (v)
1	Diagnosis (WD & DD)		
2	Dasar Diagnosis		
3	Tindakan Kedokteran		
4	Indikasi Tindakan		
5	Tata Cara		
6	Tujuan		
7	Risiko		
8	Komplikasi		
9	Prognosis		
10	Alternatif & Risiko		
	Lain-lain		
Dengan ini menyatakan bahwa saya telah menerangkan hal-hal di atas secara benar dan jelas dan memberikan kesempatan untuk bertanya dan/atau berdiskusi			tandatangan
Dengan ini menyatakan bahwa saya telah menerima informasi sebagaimana di atas yang saya beri tanda/paraf di kolom kanannya, dan telah memahaminya			tandatangan

* Bila pasien tidak kompeten atau tidak mau menerima informasi, maka penerima informasi adalah wali atau keluarga terdekat

PERSETUJUAN TINDAKAN KEDOKTERAN

Yang bertandatangan di bawah ini, saya , nama _____ , umur _____ tahun, laki-laki/ perempuan*, alamat _____ ,
dengan ini menyatakan persetujuan untuk dilakukannya tindakan _____ terhadap saya / _____saya*
bernama _____, umur _____ tahun, laki-laki / perempuan*, alamat _____ .
Saya memahami perlunya dan manfaat tindakan tersebut sebagaimana telah dijelaskan seperti di atas kepada saya, termasuk risiko dan komplikasi yang mungkin timbul.
Saya juga menyadari bahwa oleh karena ilmu kedokteran bukanlah ilmu pasti, maka keberhasilan tindakan kedokteran bukanlah keniscayaan, melainkan sangat bergantung kepada izin Tuhan Yang Maha Esa.

_____, tanggal _____ pukul _____
Yang menyatakan * Saksi:

(_____) (_____) (_____)

Figure 1. Example Of Consent Form for Medical Treatment

In the 2006 Manual for Approval of Medical Procedures, the KKI has prepared a standard clause format that must be stated at a minimum in the approval form for medical procedures designed by each health service facility. However, it cannot be denied that not all hospitals apply this standard clause format in practice. The 2006 Manual for Consent to Medical Procedures only compiles minimal examples of common clause formats for approval of medical procedures. Because hospitals or health service facilities in Indonesia are very diverse in classification, starting from type type. So on, each hospital carries out developments or improvisations according to the nature of the actions needed by patients. Informed consent *was* made by the hospital. Implications of standard clauses in informed consent will have a good impact if medical professional standards, hospital operational standards, and medical needs prepare the standard clause informed consent. Whether or not there is an impact from the traditional class informed consent depends on the guidelines compiled (Dali et al., 2019).

Standard clauses in *informed* consent will always help patients and doctors if the hospital prepares standard clauses to write down all medical information as completely as possible and by all established standards. In practice, there are concerns that if standard clauses are formed, informed consent by the hospital or doctor first will result in the principle of freedom of contract not being fulfilled, and the hospital or doctor only needs the patient's signature. This can be said to be wrong because informed consent, which was formed and intended to provide an explanation as well as perform invasive actions unilaterally by the patient, does not violate the principle of freedom of contract because the consent of the patient is already an appreciation for his release and self-awareness as a patient to perform invasive actions or surgery on his body after the doctor has given a detailed explanation and the patient has fully understood the medical act. Then, the statement that the hospital or doctor only cares about the patient's signature must be corrected. In addition to being poured into informed consent, all medical information must first be explained to the patient (Wahyuni & Sugiarti, 2017).

The doctor who makes the diagnosis and recommends medical action must provide as complete an explanation as possible regarding medical information. The patient has the right to ask questions until he fully understands the medical action that will be carried out on him. Therefore, it cannot be said that the standard clause violates the principle of freedom of contract or only prioritizes the patient's signature. Standard clause informed consent manifests the initiative of doctors and hospitals as parties with more expertise to form the main guidelines for doctors and patients in carrying out health services et al.(Tajuddin & Pieter, 2021).

Standard clause informed consent are rules or terms and conditions related to medical information in therapeutic transactions prepared and determined unilaterally by the doctor or hospital. If we analyze the standard clause, informed consent has provided all forms of medical information, such as (1) the identities of the parties, (2) information regarding the medical action to be carried out, and (3) the signatures of the parties.

When referring to forms of legal protection, the use of standard clauses in informed consent has increased forms of preventive legal protection. This form of increasing preventive legal protection means establishing standard clauses. Informed consent will improve the completeness of the information contained in informed consent. Then, it will become guidelines or rules that can explain the rights and obligations of the parties and protect the rights of the parties. Apart from that, the provisions have been stated in standard clauses as a form of legal protection. Informed consent will be used as an initial guide regarding the contents of the approval for medical action that the patient agreed to with the doctor, a measuring tool for whether there are elements of legal violations, disciplinary violations, or ethical violations of medical practice, the foundation of the doctor's medical actions by medical professional standards, standard operational procedures, and the patient's medical needs, and can protect both

parties from medical risk disputes that arise. Therefore, it can be concluded that the implications of the standard clause in informed consent have increased compliance with the principles of legal protection for patients, doctors, and health service facilities.

2. Implementation of the Use of Standard Clauses in Therapeutic Transactions in Court Decisions

One of the cases discussed is Decision Number 63/Pdt.G/2021/PN Kpn, which started with a patient with the initials W.T. He was admitted to W Hospital on May 24, 2018, because he was bleeding. After an examination, the patient was immediately admitted to W Hospital in the class II category because of quite a lot of bleeding. While undergoing treatment in the emergency room, hospital W offered 5 (five) obstetrics and gynecology (Sp. OG) specialist doctors to the patient and her husband. They also chose Doctor R as the specialist to treat the patient. Then, on May 25, 2018, the patient was taken to Doctor R's polyclinic for further examination. After the study, the patient's husband asked Doctor R about his wife's illness. Doctor R explained that the patient had a myoma measuring 12 (twelve) cm. After being presented, the nurse said the patient was advised to undergo surgery. However, because the patient used the Social Security Administering Agency (BPJS), he was asked to go home first.

During the patient's hospitalization from 24 – 28 May 2018, the patient was given a blood transfusion. As a result of the initial examination, doctor R asked a radiology specialist, namely Doctor M, to examine him, and Doctor M also gave a clinical diagnosis that the patient had pro-op uterine myoma. After receiving the results of the clinical diagnosis, Doctor R told the patient that the patient was advised to undergo surgery to remove the uterine myoma, and the patient agreed to undergo surgery on May 31, 2018. After being treated for 4 (four) days, the patient was allowed to go home and prepare himself for the planned operation. However, on May 29, 2018, the patient came and underwent another examination because the patient was bleeding. Then, the surgery schedule, which was initially to be carried out on May 31, 2018, was moved forward to May 30, 2018. During the second examination, doctor R asked an anatomical pathology specialist, doctor D, to examine the patient. After reading the patient, doctor D stated a clinical diagnosis of Myoma uterus + Cystoma ovaria sinistra.

Based on this clinical diagnosis, on May 30, 2018, at 15.00 – 18.00 WIB, surgery was performed to remove the uterine myoma and ovarian custom. Then, after the operation, at around 18.30 WIB, the patient experienced nausea and vomiting. The patient also asked the nurse to call Doctor R, but at that time, Doctor R could not be contacted. Because the pain did not go away, the patient asked the nurse to call a specialist doctor, but at that time, there was no obstetrics and gynecology specialist on site. At that time, there was only a doctor on duty, and the doctor on duty treated the patient until his pain subsided, and he could rest.

On June 1, 2018, at 08.00 WIB, Doctor R visited the patient in the inpatient room. In the afternoon, doctor R allowed the patient to go home and advised the patient to have another check-up on Monday, 4 June 2018. Following Doctor R's recommendations, the patient had a check-up on 4 June 2018. The patient was examined by Doctor Y. Two months later, the patient experienced nausea and dizziness like a pregnant person. With that, the patient came to the Community Health Center for a urine test, and the results were negative. The patient also received a referral, and the patient decided to carry out further examination at Hospital W. While at Hospital W, the patient was examined again by Doctor Y, and the result of the study was that the patient's uterus had been removed. Hearing the examination results, the patient filed a complaint with W Hospital.

On August 2, 2018, the duty manager contacted the patient, and the hospital was asked to see Doctor R for further explanation. The next day, the patient saw Doctor R for a reason regarding the operation two months ago. In the meeting with Doctor R, he joined case manager W hospital. Doctor R admitted that the surgical process carried out was for the removal of myoma uteri and cystoma ovaria

sinistra as well as the removal of the uterus or Total Abdominal Hysterectomy (TAH). Hearing the explanation from the patient felt disadvantaged because the patient felt that Doctor R never explained to the patient either before or after the operation. Apart from that, the patient said that only the nurse provided medical care, and the nurse only provided information that the myoma uteri and cystoma ovaria sinistra would be removed. Because of this information, the patient agreed and signed informed consent given by the nurse. The patient stated that Doctor R was unprofessional and dishonest because he did not provide a detailed explanation regarding the medical diagnosis, procedure for the procedure, aim of the course, alternative strategies, possible complications, and prognosis for the process to be carried out.

Meanwhile, the patient also felt disadvantaged by the operation carried out by Doctor J without the patient's consent. Then, the patient reported the alleged disciplinary violation to the Disciplinary Honor Council. After the examination, on February 20, 2020, the Disciplinary Examination Council (MPD) read out Decision Number 14/P/MKDKI/IV/2019 regarding the complaint submitted by the patient. The decision stated that there was no violation of medical professional discipline against the defendant or doctor R. Feeling dissatisfied with the examination results and the MKDKI's decision, the patient filed a lawsuit regarding unlawful acts and negligence committed by hospital W, doctor R, and doctor J.

If you look at the case above, the central claim from the patient stated that the defendant had committed an unlawful act because he had performed surgery to remove the uterus or TAH without the knowledge and permission of the patient or his family. Then, because of these actions, the plaintiff suffered material and immaterial losses. Meanwhile, the defendants revealed in their answer that hospital W had a Standard Operating Procedure (SOP) in serving incoming patients, doctor R had explained the medical actions to be carried out to treat the patient's myoma, and Doctor J had never replaced the doctor R in carrying out TAH operations.

In its legal considerations, the Panel of Judges at the Kepanjen District Court has always used the study of medical practice science as a basis for forming its judges' considerations. The judge's considerations have referred to the provisions of the Medical Practice Law, Minister of Health Regulation Number 290 MENKES/PER/III/2008, and the Medical Procedure Approval Manual, which outlines the provisions regarding the rights and obligations of patients and doctors in carrying out therapeutic transactions, one of which is the obligation to ask for patient consent before undergoing medical procedures et al.(Setyawan & Hadiyati, 2021). Meanwhile, documents that can reveal the fact that approval has been given and contain the provisions for carrying out approved medical practices are stated in informed consent. In the judge's consideration, the civil judge has considered informed consent as a valid and robust evidence tool in court.

If further analyzed based on the judge's considerations, hospital W and doctor R have carried out the obligations of doctors and the obligations of service facilities in carrying out medical practice. This can be seen in the fact that W Hospital has standard SOPs regarding procedures that must be carried out when carrying out medical practice, one of which is carrying out informed consent. Before the patient underwent surgery, the hospital team W and Doctor R provided all information regarding medical procedures and several written documents, namely documents providing information and approval for medical procedures.

The construction of documents providing information and approval of medical procedures prepared by Hospital W and Doctor R can be said to have a legal force which offers legal protection both preventively and repressively for the fact that Hospital W and Doctor R have carried out medical practices by provisions agreed to by the patient and his family. Because this case has entered the legal

arena, informed consent has provided repressive legal protection because informed consent will be the primary evidence that is strong and valid as a guide to whether a disciplinary violation or violation of the law has occurred.

With that, it can be said that the Panel of Judges at the Kepanjen District Court has considered all the evidence provided by the defendants. The main evidence is in the form of documents giving information, approval of medical procedures, and expert testimony in accordance with legal provisions in Article 45 and Article 51 of the Medical Practice Law. This evidence has provided legal protection to doctors R and Hospital W by disclosing that the defendants have carried out TAHBSO actions for valid reasons and have carried out obligations based on SP, SOP, patient medical needs, and existing laws and regulations by providing explanations regarding the actions. Medical care is to be given and obtain consent from the patient and their guardian. Therefore, the defendants were declared not to have committed any unlawful acts, and the plaintiff's lawsuit was rejected.

CONCLUSION

Based on statutory theory, normatively standard clauses do not violate the principle of freedom of contract because they are standard clauses. Informed consent in Therapeutic Transactions is a manifestation of the initiative of doctors and hospitals as parties who have more expertise to form the main guidelines for doctors and patients in carrying out health services as stated in the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions which regulates in detail regarding the obligation to carry out informed consent in therapeutic transactions and the 2006 Medical Action Approval Manual prepared by the Indonesian Medical Council which is a guide for hospitals and doctors in preparing frameworks and standard clauses informed consent.

Based on the analysis of Decision Number 63/Pdt.G/2021/PN Kpn, the use of standard clauses informed consent The therapeutic agreement provides repressive legal protection in trials. It has a positive influence, namely strengthening informed consent as strong and valid evidence in the trial. It has guided whether the medical action was carried out according to the approved motion, SP, SOP, and patient need.

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