The Principle of Consensualism in Informed Consent Between Doctor and Patient

Lintang Yudhantaka, Mas Anienda Tien Fitriyah, Rosalia Dika Agustanti*

Abstract

The term informed consent or consent for particular medical treatment was familiar in medical world. It brought security for both doctors who did their profession and patients who got information about the illness they were suffering from along with any medical treatment they would have. In fact, there were still many problems issued due to less-well implementation of informed consent. Therefore, this study aimed to analyze the characteristics of informed consent as the legal basis between doctor and patient and verify the establishment of agreement (i.e., consensus) in informed consent. It was a juridical-normative research with conceptual and statute approaches. The result of this study found that informed consent had distinctive characteristics compared with any other common agreements, in particular to its subject, object, and cause. Towards the establishment of consensus, it referred to the doctor’s offering to do any medical treatment and patient’s acceptance to have that treatment.

Keywords

Informed consent; Agreement; Consensualism

* Faculty of Law, University of Pembangunan Nasional Veteran Jawa Timur (UPNJVT), University of Pembangunan Nasional Jakarta (UPNVJ)

Correspondence: Lintang Yudhantaka, Faculty of Law, University of Pembangunan Nasional Veteran Jawa Timur (UPNJVT), Surabaya, Indonesia. Email: lintang.ih@upnjatim.ac.id.
Introduction

Health is something that every person always wants to have. Without any good health, people may not do their daily activities well. In line with the term “preventing is better than curing”. It indicates that health is a precious thing that every person should maintain. When someone is sick, no one can guarantee when she/he may get well and how much money she/he should spend for medical treatment. Hence, health should be well maintained.

Health is also one indicator of nation’s welfare, and it is a human right that must be preserved. The Republic of Indonesia accommodates it by mentioning this issue in Article 28H subsection (1) of the Constitution of the Republic of Indonesia 1945 (later called UUD NRI 1945). The article mentions that every individual deserves good life physically and mentally, good living, good and healthy environment, and deserves good healthcare.

Maintaining good performance of healthy and fit body is everyone’s wanting. They do a lot of efforts, both preventive and repressive, to maintain their health. The preventive effort refers to implementing a healthy lifestyle such as having daily exercise and consuming food with good nutrient. Repressive effort deals with taking any medical treatment by seeing doctor for health recovery (Sumilat, 2014: 55). Towards this repressive effort, an activity commonly called medical practice is organized.

Article 1 subsection (1) of Act No. 29/2004 about Medical Practice (later called the Act of Medical Practice) mentions that medical practice refers to a set of activities by general doctor or dentist on their patient for medical treatment. Organizing medical practice is the main part of implementing medical treatment by doctor. Indeed, the doctors who organize medical practice may not neglect the standards of medical profession and should uphold the moral ethic, have adequate competence, license, certifications, and any other requirements as mentioned in Preamble of Act of Medical Practice.

The relationship between doctor and patient happens on which they organize a medical practice, and this relationship evokes an engagement between them. Article 1233 Burgerlijk Wetboek (later called BW) mentions that every engagement is established due to either contract or legislation. It is similar with the relationship between doctor and patient. So far, doctor-patient legal relationship is classified into 2 (two) categories including due to contract (i.e., therapeutic transaction) and due to legislation (i.e., zaakwarneming) (Ali, 2006: 14).

This study focused on a discussion about doctor-patient legal relationship that happened due to contract/agreement. Article 1313 BW explained that what was meant by agreement referred to a measure through which one or more people engaged themselves with one else or others, and thus, a legal relationship between two or more people happened and each of the engaged parties had their own rights and responsibilities.
Basically, the relationship between doctor and patient relies on 2 (two) kinds of individual basic rights; the right of self-determination and the right to healthcare. These two basic rights generate patient’s rights to have information about their health/illness (Soewono, 2006: 8). It should be noted at first that doctor-patient relationship comes from trust (paternalistic) which turns into partnership and leads to contractual relationship. Hippocrates mentioned this doctor-patient relationship as therapeutic transaction (Soewono, 2006: 51).

In therapeutic transaction, it begins with question-and-answer (i.e., anamnesis) between doctor and patient (Ali, 2006: 9). Afterward, the patients give complete and honest information about their health issue. They should also previously agree that their personal rights were violated after having information from their doctor about any medical treatment they should go through for their healthcare. The doctor will implement the medical treatment after he had the patient’s agreement. In medical field, this is called Informed Consent (Ali, 2006: 22).

Positive law in Indonesia does not explicitly mention about informed consent. However, the applied term is Agreement of Medical Treatment which regulation is mentioned in Health Ministerial Regulation of the Republic of Indonesia No. 290/MENKES/PER/III/2008 about Agreement of Medical Treatment (later called Permenkes 290/2008). This Permenkes 290/2008 is an applied rules based on the mandate of Article 45 of Act of Medical Practice. Article 1 subsection (1) of Permenkes 290/2008 explains that what is meant by the agreement of medical treatment refers to the consent that patient or the closest family/relative gives after having complete and detail explanation about any medical treatment they may go through for their healthcare.

Ironically, although the government has enacted the legal law dealing with informed consent, phenomena of healthcare at some hospitals in Indonesia which show a number of malpractice cases happen which actually come from not-well implementation of informed consent. One of the cases is such as the constriction of blood vessels suffered by Zacky Arya Pratama (8 years old) in Regional Public Hospital Sultan Imanuddin Pankalan Bun, West Kotawaringin, Middle Borneo (Dzakwan, 2017). Another case of malpractice was suffered by Badriah who has wrong blood transfusion in Arun Hospital, Lhokseumawe (Aidil, 2017).

A patient and his/her family give their trust to doctor to give a medical treatment for the sake of the patient’s health. It is very unfortunate if a doctor who has given his best effort to do an optimal medical treatment but comes into a bad result which brings the patient to worse condition or even death should be responsible due to his negligence of not implementing the procedures well, especially those dealing with informed consent.

In principle, Informed consent is an agreement. As we know, agreement is made in both written and non-written (verbal). Similarly, informed consent can be made both written and verbal (vide of Article 45 subsection (4) of Act of Medical Practice). Towards written informed consent, some clauses should be mentioned. Although it refers to an agreement
in principle, informed consent has distinctive characteristics compared with any other common agreements. Just like sell-and-purchase agreement, rent, agency, distributor, and any other agreements with their characteristics, informed consent has its own characteristics as it is not purely a business contract, but solely a medical contract.

Based on the description of the introduction above, the legal issue to be discussed is the characteristics of informed consent as the basis of legal relationship between doctor and patient. Besides that, this article will also discuss about verifying the element of consensus in Informed Consent.

Research Methods

A study of juridical-normative is used, considering the exclusive character of the study itself which method is normative. This method is useful to analyze the correlation of legal regulations, jurisprudence, and contracts. As this study is a normative research, statute and conceptual approaches are applied. Statute approach is applied by examining the legislation and other related legal regulations on intended legal issue. It is an approach using legislation and regulation. In addition, conceptual approach is applied by using the perspectives and concepts from some experts to analyze the data collected, along with any growing doctrines in the discipline of law as the basis of this study in order to construct the argumentation of law to solve the studied legal issue (Marzuki, 2009: 93).

Discussion

1. Characteristics of Informed Consent as The Basis of Legal Relationship between Doctor and Patient

In this current pandemic era, medical fields become an area with the most spotlights since they play fundamental roles as a front liner that fights against the pandemic. The big responsibility along with the very high risk they must carry out makes government consider making a regulation as a legal basis for doctors and medical staffs. However, many issues happen dealing with the notion of malpractice. It is because common people mostly have less understanding about medical field. They tend to see the performance of doctors and medical staffs from the final result, not from their efforts.

It should be noted that informed consent in this therapeutic agreement is different from any other common contracts. The difference is on the agreed object (Mahendra, 2011). In law of agreement, there are two kinds of engagements, including (Ali, 2006: 19):

1) Inspanningverbintenis, it is an engagement promising efforts, in which both engaged parties promise or agree to do their best efforts to achieve what they have promised in their agreement.

2) Resultaatverbintenis, it is an engagement promising results, through which it must carry out the actual result it has promised.

Generally, doctor-patient relationship is a legal relationship which orientation refers to an optimal effort. Although doctors may not promise patient’s recovery as it is out of
their capacity as human, they can do their best for the sake of their patient’s health. Therefore, the legal relationship between doctor and patient is actually classified into *inspaningverbintenis*. In some conditions, however, doctor-patient legal relationship which orientation refers to results (i.e., *resultaatverbintenis*) may happen such as making fake teeth by dentist, or fake parts of body by orthopedist or plastic surgeon (Ali, 2006: 11).

Common people may not understand about this kind of classification, and thus, it tends to emerge misunderstanding. This misunderstanding often ends with lawsuit. In order to avoid any lawsuit of malpractice in case that the patient is not familiar with medical field, therefore, it needs a mechanism of informed consent as a preventive effort (Kinanti, 2015: 112). Before discussing the characteristics of informed consent, the conditions of validity for an informed consent should be previously elaborated in order to reach the characteristics of informed consent itself.

Basically, Informed consent is an agreement. To protect a legal relationship between parties, the agreement should be legally made. An agreement is considered legal and legitimate when it meets some conditions dealing with the legitimation of agreement as mentioned in Article 1320 BW, as follow.

1) The parties agree to get engaged (agreement/*toestemming*);
2) Proficiency to make agreement (proficiency/*bekwaamheid*);
3) Particular matter (particular object/*een bepaald onderwerp*);
4) An allowed cause (cause/*oorzaak*).

Towards those four conditions, Article 1320 BW also gives further explanation about the consequence of not fulfilling them. The first and the second are subjective because they deal with the engaged parties or subject. The third and fourth are objective as they deal with the agreement itself or the object of the legal agreement (Subekti, 2014: 17).

Not fulfilling one or more of those four conditions as mentioned in Article 1320 BW, either subjective or objectives conditions, may bring some effects as the consequence, such as (Nieuwenhuis, 1985: 1):

1) Non-existence, no agreement reached means no contract.
2) *Vernietigbaar* or the contract can be nullified if it is established due to default action (*wilsgebreke*) or the lack of proficiency (*onbekwaamheid*) – (article 1320 BW the first and second conditions), hence, it deals with subjective elements, which brings a consequence that the contract can be nullified; and
3) *Nietig* or null and void, when the agreement fails to meet the conditions of particular object or allowed causes (Article 1320 BW, in particular to the third and fourth conditions), hence, it deals with objective elements, which brings a consequence that the agreement can be null and void.

The following section explains each of those conditions mentioned in Article 1320 BW that deals with informed consent.
a. Agreement

Agreement (stem from the term agree) refers to a statement of the conformity of will (overeenstemende wilsverklaring) between parties, through which the offering (offerte) meets acceptance (acceptatie) (Badrulzaman, 1983: 98). Besides, any defect of will should be considered as well. Based on Article 1321 BW, an agreement between engaged parties may become illegal when any defects of will such as mistakes/errors, coercion, and/or deception is found as the cause of making the agreement. As time goes by, the kinds of defect of will are not only what have been mentioned in Article 1321 BW. There is one new defect of will called the misuse of condition (misbruik van omstandigheden). This doctrine can be found in the Verdict of The Supreme Court of the Republic of Indonesia No. 3431 K/Sip/1985, or commonly called “the Case of Pension Book”. It concludes that the defect of will involves errors or mistakes (dwaling), coercion (dwang), deception (bedrog), and the misuse of condition (misbruik van omstandigheden).

Towards informed consent, agreeing indicates the conformity of will in which the doctor offers medical treatment (offer) and the patient accepts it (acceptance). In order to make the doctor-patient agreement legal, it may encounter any defect of will, as previously explained. Therefore, it needs informed consent or commonly called as the agreement for medical treatment (Busro, 2018: 6).

b. Proficiency

Based on the current law, every person is considered proficient (has an authority) for making an agreement, except those in the following categories (vide article 1329 jo. 1330 BW):

1) Those who are Under-aged/immature;
2) Those who are under support.

In addition to those 2 (two) criteria, the third criterion refers to women, as ruled by law, for every individual in general, for whomsoever the law has forbid to make particular agreement. However, this substance is no longer applied due to some conditions that make this criteria removed. First, the Circular letter of the Supreme Court No. 3/1963 stating that wife remains proficient in action by pulling out the regulation of Article 108 and 110 BW. Article 31 Act No. 1/1974 about Marriage (later called UUP) also explains that husband is the head of family, while wife is the mother of household, but each of them has equal position, and they have rights to take any legal actions.

Towards immature people, the establishment of UUP mentions that an individual is considered mature when they reach 18 (eighteen) years old or ever get married.
as mentioned in Article 47 jo. 50 UUP. It is supported by the Supreme Court of the Republic of Indonesia through the Instruction of Supreme Court No. No. MA/Pemb/0807/75 and the verdict of Supreme Court No. 477K/Sip/1976, on 13th October 1976 (Satrio, 1992: 279). Towards under-support people, Article 433 BW mentions that they refer to idiot (onnoozelheid), people with mental illness, ‘burst a blood vessels’ people (razernij), and wasteful people. Actually, they remains under support although sometimes they can act proficiently (Fuady: 1999: 70).

Towards informed consent, the acceptor of medical treatment can be various on their categories of age and proficiency, either good or bad in action. Doctors should realize it as they engage themselves in informed consent for therapeutic transaction in order to avoid any dispute in the next future (Busro, 2018: 7).

c. Particular Object

Particular object or matter as the third condition mentioned Article 1320 BW deals with the performance promised in the agreement (Hernoko, 2010: 191). Munir Fuady (1999: 87) defines “performance” in law of contract as the implementation of any matters mentioned in a contract between engaged parties, which implementation corresponds to the “term” and “condition” mentioned in the pertinent contract. Meanwhile, Agus Yudha Hernoko (2010: 242) explains that performance, in law of contract, is defined as “what to do” by engaged parties according to the agreement they make. In addition, Mariam Darus Badrulzaman (1983: 7) defines performance as the obligation to reach something or refers to the legal object.

In relation to informed consent, the object of this agreement refers to the medical treatment itself, which involves the acts of prevention, healing, and recovery (Wicaksana and Budhisulistyawati, 2019: 153), in which those all treatments are effort-oriented, not result-oriented. As previously discussed, informed consent is basically classified into inspaningverbintenis category. Therefore, doctors are not allowed to guarantee any result of their efforts. Patients’ recovery does not only depend on a doctor’s persistence, but also his proficiency in performing his professional work. Furthermore, it depends on some other factors such as patients’ resistance, the stage of illness, and patients’ commitment during the process of their recovery as the doctor has instructed for the sake of their own health (Kinanti, 2015: 110).

d. Cause

Wirjono Prodjodikoro (2000: 37) argues that cause in a legal agreement refers to the content and intention, which brings on the agreement. Understanding the definition of the term cause which becomes the fourth condition mentioned in Article 1320 BW, J.H. Nieuwenhuis correlates it with Article 1335 and 1337 BW. In this context, the definition of cause refers to the intention (causa finalis) that the
engaged parties want to achieve with the agreement or the goal of making the agreement itself (Nieuwenhuis, 1985: 25).

A condition that the cause of an agreement must be allowable should be considered in the principle of freedom of making contract. Basically, the engaged parties are free to define the content of their agreement. The function of defining allowed cause is in line with a desire to block the freedom of creating contractual agreement in fit and proper boundaries. If the engaged parties want something off-limits against the applied law, propriety, morality, and public norms, the agreement they want to achieve will be null and void (Nieuwenhuis, 1985: 26).

In the context of informed consent, for instance, abortion is a doctor-patient agreement which cause is not allowable or banned, but due to any specific medical issue that may affect the patient’s life, as mentioned in Article 75 subsection (2) of Health Law No. 36/2009 about Health (later called Law of Health). Meanwhile, providing medicines by doctors to patients for the sake of patients’ recovery is one example of allowed cause, as mentioned in Article 63 subsection (2) of Health Law.

Overall, it concludes that the characteristics of informed consent in therapeutic transaction refer to its subject, object, and cause. Towards its subject, the engaged parties are the doctor and patient. The relationship between doctor and patient relies on partnership in which the doctor is someone with insights, qualification, and competence in medical field while the patient is someone that needs help from a professional and qualified one called doctor. Towards its object, it refers to the doctor’s medical treatment for patient’s recovery. Furthermore, the cause of informed consent refers to agreeing with any treatment that may improve patient’s health (promoting), prevent any illness (preventive), and cure any illness (curative), as well as patient’s recovery (rehabilitative) (Komalawati, 1999: 145).

2. Verifying the Element of Consensus in Informed Consent

Basically, every person has an obligation to create, maintain, and enhance the level of their health as high as possible. It is mentioned in Article 9 subsection (1) of Health Law. However, as human is zoon politicoon (Huijbers, 2018: 28), they need helps from others with medical competence to encounter their health issues. In medical world, the helper (e.g., doctor and medical staff) needs to give adequate information and explanation to patients about their medical condition in order to give an optimal service. It solely aims to make the patients understand their actual condition and give their real consent in accordance to what they have understood. The correlation between information and consent is mentioned in an informed consent (Komalawati, 1999: 104).

The presence of informed consent has a double function for both doctor and patient. In one part, informed consent give security for doctors to do their professional function on patients, and at the same time, it can become an instrument to protect them from any possible lawsuit that patients or patients’ family may file due to unexpected result. In another part, informed consent is a manifestation of patients’ rights to have information
about their illness, medical treatment they may go through, any possible complications as the effect of the treatment, another alternative therapy, and proposition (Astuti, 2009: 88).

As previously discussed, informed consent is essentially based on a consensus. To make the consensus legally legitimate, it should avoid any defect of will such as mistakes (dwaling), coercion (dwang), deception (bedrog), and the misuse of condition (misbruik van omstandigheden). The following section will explain them in more detail.

The element of mistakes or error (dwaling) is considered found on which someone makes an agreement with wrong perspective or impression (Fuady, 1999: 42). Errors as mentioned in Article 1322 BW involve errors in person (error in persona) and error in substance of agreement (error in substantia) (Badrulzaman, 1983: 100).

Towards coercion (dwang), Article 1324–1327 BW mentions that it happens when someone decides to make an agreement (give his consent) under pressure or threat against the law (Hernoko, 2010: 171). The threats against the law are classified into two categories, including (Nieuwenhuis, 1985: 19):

a. The threat is truly against the law (e.g., murder, oppression, fake report);
b. The threat is not against the law, but it aims to get something that cannot be reached.

Furthermore, deception (bedrog), as mentioned in Article 1328 BW, is a guile that someone uses in order to make another party wants to sign their agreement. Unless getting trapped by the guile, the engaged party will not sign the agreement (Fuady, 1999: 38). The guile must be substantial. The emphasis relies on a set of guile that makes another party agree to do what they want, or otherwise, disagree or even propose another alternative in case that they know about the deception (Hernoko, 2010: 172).

Towards the misuse of condition (misbruik van omstandigheden), it is a new element on the defect of will, and it is mentioned in Nieuw Burgerlijk Wetboek (NBW) in Nederland. This misuse of condition which may injure another party refers to the misuse of occasion by someone. Van Dunne classifies the occasion into two categories, as follow (Hernoko, 2010: 177):

a. The misuse of economy privilege, when one of the engaged parties has economy privilege on another party that makes them forced to make a contract (for instance: in some cases between banks and their customers).
b. The misuse of mental privilege, on which one of the engaged parties misuses a relative dependence (e.g., doctor-patient, advocate-client) or specific mental condition that another party may have (e.g., mental illness, less experience, or less knowledge)

Therefore, it notifies that as long as an agreement or informed consent is created due to the defect of will, the agreement is illegal. Given that consent is a subject element for legally creating an agreement, therefore, it can be nullified if the consent is reached through some ways against the law. Moreover, what should be considered in informed
consent is the doctor’s obligation to give detail information about patient’s condition before they reach the patient’s consent for conducting particular medical treatment. Towards any information or explanation they must deliver, Article 45 subsection (3) of Medical Practice Law mandates that any information that doctors inform to patients must at least involve:

a. Diagnosis and the procedures of medical treatment;
b. Aims of conducting the medical treatment;
c. Another alternative treatment along with the risks;
d. Any possible Risks and complication; and
e. Prognosis of the treatment.

Additionally, Permenkes 290/2008 which is the implementing regulation of Article 45 of Medical Practice Law, in particular to Article 7 subsection (3), has similar regulation as what is mentioned in Article 45 subsection (3) of Medical Practice Law. However, it adds one extra point that deals with the estimation of expense. Therefore, there are at least 6 (six) points that doctors should inform before conducting any medical treatment on their patients, those are:

a. Diagnosis and the procedures of medical treatment;
b. Aims of conducting the medical treatment;
c. Another alternative treatment along with the risks;
d. Any possible Risks and complication;
e. Prognosis of the treatment; and
f. The estimation of expense.

Towards the way of delivering informed consent, Article 45 subsection (4) of Medical Practice Law explains that informed consent or the agreement for medical treatment can be delivered in written or oral. Some literatures explain that both written and oral informed consents are classified into expressed consent (Mayasari, 2017: 178). Oral informed consent is usually for low-risk medical treatment (non-invasive) such as providing therapeutic medicines and medical check-up (Kinanti, 2015: 111). As like its name, oral informed consent emerges when both doctor and patient express the conformity of will between them orally. On the other hand, high-risk invasive medical treatment needs a written consent as mentioned in Article 45 subsection (5) of Medical Practice Law. Having surgery is one of the examples. Written informed consent is a must (Komalawati, 1999: 109). It is because written informed consent brings more legal assurance among the engaged parties, especially those dealing with therapeutic transactions. Moreover, in case of a dispute between the engaged parties, the written informed consent can be used as the primary evidence in the process of investigation.

In addition to expressed consent, there is another form of informed consent commonly known in medical field. It is implied consent (implicit) (Pakendek, 2010: 313). Generally,
implied consent is commonly for normal situation, in which doctors may see the patients’ consent from some signals that patients give. For instance, when a doctor wants to either test a patient’s blood pressure or give an injection, the patient immediately stretch out one of his arms as a sign that he agree for that treatment (Stanley, Walters, and Maddern, 1998: 788-791). Another signal is like nodding which indicates that the patient agree for particular treatment his doctor will implement on his body. Similarly, patients’ gestures that allow or accept the treatment without any rejection seem to be the signal of patient’s consent (Kinanti, 2015: 111).

In accordance to the two types of informed consent previously discussed, it shows that the agreement of medical treatment always involves the element of voluntary by patients to accept particular medical treatment by their doctors (Syafuddin and Anand, 2015: 170). Besides, informed consent also requires the element of disclosure which makes doctors able to get detail information that deals with their patients, including family and other relatives engaged in patients’ surroundings. Hence, doctors can be more careful and thorough in diagnosing their patients by implementing the principle of prudence (Syafuddin and Anand, 2015: 169).

Providing adequate information or explanation to patients is, indeed, the part of professional and procedural standards for a doctor. In case that he neglects it, the doctor will be sentenced by, at least, I (one) year in prison or be charged by fine up to Rp 50.000.000,00 (fifty million rupiahs) at most, as mentioned in Article 79 of Medical Practice Law. Therefore, a clause stating that the doctor has provided information and explanation about things mandated in Article 45 subsection (3) of Medical Practice Law and the patient has understood the explanation should be put into the establishment of informed consent and verified by signatures among parties. It aims to give more legal assurance for both engaged parties.

In case that the doctor has provided information or explanation and the patient has understood, the patient has rights to either accept or refuse the proposed medical treatment, as mentioned in Article 52 letter (d) of Medical Practice Law. The article explains that patient has rights to either accept or refuse any medical treatment. Thus, both doctor and patient should have the conformity of will and the same understanding about the information and explanation provided although does not always bring them into particular medical treatment. The implementation of any medical treatment depends on patient’s consent. However, in some conditions (e.g., in case of emergency), it does not need any consent.

Overall, it concludes that informed consent in therapeutic agreement is a manifestation of implementing the principle of consensualism which is an essential element in a legal contract. Furthermore, Article 1320 BW mentions that consent is the first condition. As previously discussed, an agreement can be legally nullified if it is established due to any defect of will. Similarly, an agreement will never exist without any consent from both engaged parties.
Conclusion

Basically, informed consent is also an agreement which implementation needs to consider some terms and legal conditions. Looking into its characteristics, informed consent has some distinctive elements compared to any other contracts in general. First, the subject consists of doctor and patient. In this context, doctor is someone with medical competence and proficiency, while patient is someone that needs professional medical service by the doctor. Given that informed consent is a kind of *inspaningverbintenis* agreement, the promised object refers to the doctor’s service which is healing-oriented, not result-oriented. Towards its cause, the establishment of informed consent solely aims to improve patient’s health (promoting), prevent any illness (preventive), and cure any illness (curative), as well as patient’s recovery (rehabilitative).

Considering its types, Informed consent is classified into explicit (i.e., expressed consent, either orally or in written) or implicit (i.e., implied consent). If the informed consent is granted orally, it emerges since the doctor offers particular medical treatment and the patient is willing to accept the treatment (acceptance), and both of them express their willing orally. If the informed consent is granted in written, the agreement between the engaged parties is seen from their signatures on the informed consent form. Towards implied consent, it is seen from the signals that the patient gives to the doctor, such as nodding, stretching out the arm for injection, or no rejection from the patient against the medical treatment.

References


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