

Philosophical Basis of Informed Consent, Informed Refusal and Documentation of Medical Information into Medical Record

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ABSTRACT

Information delivered by the medical professionals to the patients in their initial communication is crucial in establishing the therapeutic contract (transaction). Based on that information, the patient will decide whether to accept or to refuse the proposed medical treatment. This paper discusses the philosophical basis of the Informed Consent, Informed Refusal and the documentation of medical information into Medical Record. This normative legal research is carried out by library-based study on primary and secondary legal materials. Besides descriptive-analytical approach, the study also employs comparative approach. The comparison is made between continental legal system, common law system, and the Islamic legal system. It is found that philosophical basis of informed consent, informed refusal and documentation of medical information into medical record is basically to protect the patients' dignity and to maintain their trust and cooperation. Furthermore, from the Islamic perspective the establishment of informed consent is to respect the privacy to blood, property, and family. In addition, the documentation of medical information into the medical record is to give legal protection in the form of strong evidence both for the health providers and health receivers in the event of a medical dispute.

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1. Introduction

Healthcare service especially in the form of medical treatment creates a legal relationship between healthcare receiver (patient) and healthcare provider (doctor and/or hospital). The nature of the mentioned legal relationship is contractual, and this

contractual relationship is commonly referred to as therapeutic contract. As a form of contract, therapeutic contract requires the element of agreement (consensus) between the patient and the hospital or medical professional. This element is reflected in a legal document called Informed Consent. Once the consent is given by the patient, the therapeutic contract is concluded and therefore it is legally binding for related parties; the doctor and/or hospital in one side and the patient in another side.

Informed Consent is governed generally in the Health Act 2009 (*Undang-undang Nomor 36 Tahun 2009 tentang Kesehatan*) and more specifically in the Medical Practice Act 2004 (*Undang-undang No 29 Tahun 2004 tentang Praktek Kedokteran*). Furthermore, Informed Consent is also governed in the Health Minister Regulation Number 290 of 2008 on Informed Consent (*Peraturan Menteri Kesehatan (Permenkes) Nomor 290/Menkes/PER/III/2008 tentang Persetujuan Tindakan Kedokteran*).

Section 56 (1) of the Health Act 2009 states that every individual has the right to accept or refuse partial or entire medical assistance that would be given to him/her after receiving and understanding the information regarding that action completely. The content of information to be given to the patient as governed in section 45 subsection (2) (3) of the Medical Practice Act 2004 consists of: (1) diagnoses and procedure for medical treatment; (2) purpose of medical treatment; (3) alternative treatment and its risks; (4) risks and complications that might be happen; (5) prognosis of treatment from the doctor and dentist.

After carrying out the medical treatment, the doctor in question is obliged to make Medical Record as determined in section 46 of the Medical Practice Act 2004. In addition, according to section 29 of the Hospital Act 2009 (*Undang-undang No 44 Tahun 2009 tentang Rumah Sakit*) the hospital is obliged to manage and store that Medical Record. Medical Record contains some notes and documents including the document of Informed Consent. Further governed on Medical Record is available in Health Minister Regulation Number 269 of 2008 on Medical Records (*Permenkes No. 269/Menkes/PER/III/2008 Tentang Rekam Medik*).

Even though it has commonly been understood that any medical treatment requires Informed Consent and that the document of Informed Consent should be inserted into the Medical Record, however in reality, there are some cases deviating from this normative requirement. Deviations relating to informed consent are various for example, there was a case that the forms of Informed Consent were not provided by the hospital. In another case, the information was not delivered in detail by the healthcare providers to the patients or their family. Such cases may lead to legal disputes between the healthcare providers and the patients.

An actual case relevant to this was a criminal case involving dr. Dewa Ayu Sasiary Prawani, dr. Hendry Simanjuntak and dr. Hendy Siagian (commonly referred to as Dr. Ayus's Case). The case took place in 2010 when these three doctors undergoing medical practice as obstetric and gynecologic resident in Dr. Kandou Hospital, Manado. They were prosecuted for having caused the death of their patient named Mrs. Julia Fransiska Makatey after the performance of cessaria. Based on the examination in the court of cassation, they were found guilty and were sentenced accordingly. As the prosecution referred to Article 359 of the Penal Code on negligent manslaughter, the accused persons must have been proven guilty for negligently caused the death of their patient. In proving the element of negligence, public prosecutor referred to the absence of informed consent for carrying out the cessaria operation. Based on the Supreme Court Decision No. 365K/Pid/2012, they were sentenced with ten months of imprisonment. Although they were acquitted based on

the latter Supreme Court decision in Judicial Review Examination, however they had ever undergone three months out of ten months imprisonment stipulated in the previous Supreme Court Decision.

Based on the above discussion, it is clear that the position of informed consent is very important in performing medical treatment. This paper will explore the philosophical basis of informed consent, informed refusal, and documentation of medical information into the medical record.

2. Method

This research is normative legal research. This normative legal research examines the legislation, jurisprudence, and doctrine to find out the philosophical basic of informed consent, informed refusal, and medical information documentation into medical records.¹ The secondary data of this research from:

- a. Primary legal material in the form of legislation and jurisprudence are the Health Act 2009 (*UU Nomor 36 Tahun 2009 tentang Kesehatan*), the Hospital Act 2009 (*UU Nomor 44 Tahun 2009 tentang Rumah Sakit*), the Medical Practice Act 2004 (*UU Nomor 29 Tahun 2004 tentang Praktik Kedokteran*), Regulation of Health Minister No 290 of 2008 on Informed Consent (*Peraturan Menteri Kesehatan Nomor 290 Tahun 2008 tentang Persetujuan Tindakan Kedokteran*), Regulation of Health Minister No 269 of 2008 on Medical Record (*Peraturan Menteri Kesehatan Nomor 290 Tahun 2008 tentang Rekam Medis*) and Supreme Court Decision No.365K/Pid/2012 (*Putusan Mahkamah Agung No.365K/Pid/2012*) and Supreme Court Decision No 79 PK/PID/2013 (*Putusan Mahkamah Agung No 79 PK/PID/2013*).
- b. The secondary legal material in the form of literature related on some issues, i.e., books, journals and research result on certain issues; also
- c. Tertiary legal materials are dictionaries and legal dictionaries.

This research also using the comparative approach to compare Informed Consent based on the continental Europe legal system, common law legal system, and the Islamic legal system.

This research was run by collecting and analyzing secondary data to obtain the legal principles, legal norms and a basic understanding of the issues discussed to find out philosophical basic of informed consent, informed refusal and medical information documentation in the medical record.

Also, the secondary data were systematically arranged and explained in order to obtain detail description about the issues discussed. Furthermore, the secondary data were analyzed to answer the problem mentioned above.

3. Analysis and Results

3.1. The Basis of Informed Consent and Informed Refusal in the Perspective of Indonesian Legal System.

The basic of healthcare efforts that are carried out by the health care providers for health receivers is a contract namely therapeutic contract. An agreement is a requirement for a contract. As well as in the Indonesian legal system, an agreement is the requirement for a therapeutic contract between health care providers and healthy

¹ Dewata, M.F.N dan Achmad, Y. (2007). *Dualisme Penelitian Hukum*. Yogyakarta. Pencil Komunika. p. 34.

receivers. Besides, the agreement is also one of the requirement for the validity of the therapeutic contract.

What is the essence of agreement or consensus? The legislation has not defined agreement or consensus, but Article 1321 of the Civil Code mentioned that: "There is no legal agreement if the agreement is given due to oversight or obtained by coercion or fraud." Therefore, based on the interpretation of *argumentum a contrario* against Article 1321 of the Civil Code, the essence of "agreement" is an agreement without any oversights or fraud, in another word it is known as "free agreement."

In health law, the free agreement is reflected in the form of informed consent. Therefore, the therapeutic contract requires informed consent. Informed consent is a legal action which relies on two kinds of human right aspect, i.e., the right to self-determination and the right to information.² According to Koeswadji³, even though the description of the right to self-determination is limited but it can be found in many international documents. Fortunately, these international documents have mentioned the general basis of the right of self-determination, for example:

a. The Universal of Human Right, which mentions in:

- 1) Article 3: "Everyone has the right to life, liberty and the security of person."
- 2) Article 5: "No one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment."
- 3) Article 9: "No one shall be subjected to arbitrary detention or exile."
- 4) Article 12: "No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attack upon his honor and reputation. Everyone has the right to protection of the law against such interference or attack".

b. The United Nations International Covenant on Civil and Political Right 1966

This provision regulates the right of the individual in various articles:

1) Article 1

All people have the right to self-determination. By virtue of the right, they freely determine their political status and freely pursue their economic, social and cultural development.

2) Article 3

No one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

The right to self-determination is closely related to the right to information because the right to self-determination is based on the ability to know and compare the existing fact then, some alternative assessment choices can be obtained.⁴

In Indonesia, the provisions governing informed consent are regulated in Article 45 of the Medical Practice Act 2004:

- (1): Every medical or dental treatment that a doctor or dentist will carry on to the patient must get informed consent.

² Komalawati, V. (2002). *Peranan Informed Consent dalam Transaksi Terapeutik*, Bandung: Citra Aditya Bakti. p. 87.

³ Koeswadji, H.H. (1988). *Hukum Kedokteran (Studi tentang Hubungan Hukum dalam mana Dokter sebagai Salah Satu Pihak)*, Bandung: Citra Aditya Bakti. p. 52-53.

⁴ *Ibid.* p.50.

(2) in conjunction with (3): Informed consent referred to the article (1) is provided after the patients have received some information, namely:

- a. Diagnosis and medical treatment procedures;
- b. The purpose of medical treatment;
- c. The other alternative treatments and risks;
- d. The risks and complications that might happen;
- e. Prognosis for the treatment taken.

Moreover, informed consent is regulated in the Regulation of Health Minister No.290/MENKES/PER/III/2008 on Informed Consent. Informed consent is the agreement of patients or patient's family for the treatment taken after receiving a complete explanation. The explanation covers:

- a. The diagnosis for the state of the patient which covers:
 - 1) Clinical findings from the results of medical check-up.
 - 2) Diagnosis of disease, at least covering initial diagnosis and differential diagnosis.
 - 3) Indication or clinical condition of patients that need medical treatment.
 - 4) Prognosis if there is medical treatment and if there is no medical treatment.
- b. The explanation of informed consent covers:
 - 1) The purpose of informed consent is for the preventive action, diagnostic, therapeutic or rehabilitative.
 - 2) The procedure of medical treatment for patients, during and after the medical treatment, and the side effects that might be happened.
 - 3) The alternative of treatment containing the advantages and disadvantages compared to the planned medical treatment.
 - 4) The risks and complication that might be happened in each alternative treatment.
 - 5) The preventive action that might be carried out if there is an emergency situation occurred because of the risks and complications or undesirable things.
- c. The explanation about the risks and complications of medical treatment is all risks and complications that might be happened after carrying out the medical treatment, except:
 - 1) The risks and complications that have been a general knowledge;
 - 2) The risks and complications that rarely happened or have light side effect;
 - 3) The risks and complications that beyond of the expectation;
- d. The explanation about prognosis covers:
 - 1) Prognosis about the life of death (*ad vitam*);
 - 2) Prognosis about the function (*ad functionam*);
 - 3) Prognosis about recovery (*ad sanationam*).
- e. Cost estimation

The explanations above have to be delivered complete with the language that eases to be understood or in another way that simplifies the understanding of patients or the patient's family. Furthermore, the explanations are recorded and documented in the medical record by the doctors who deliver the explanation and mention the date, time, name, and signature of explanation giver and receiver (Article 9 paragraph (2) Health Minister Decree No. 290 of 2008 on Medical Record).

After delivering the explanation above then, the medical treatment that will be carried out on patients requires informed consent. The informed consent can be given orally or in written form. However, for the medical treatment that has high risks and invasive

action—a medical treatment that directly can influence the integrity of the patient's body tissue, the informed consent must be in the written form.

The informed consent can be given by the patients, but in a condition that the patients cannot provide the informed consent then, the informed consent is provided by the family of patients, i.e., husband/wife, father/mother, children, siblings or the guardians.

By providing the informed consent, the consensus was reached between the patient and the doctors or the hospitals. As a consequence, the therapeutic contract is obtained between the parties. Therefore, the medical treatment that has informed consent will be the responsibility of the doctors/doctors. Meanwhile, healthcare facilities also have a role in the occurrence of informed consent.

In a condition of the patients are disagree with the medical treatment that will be carried out after receiving the explanation from the doctors, the patients can propose the informed refusal. The informed refusal has to be in written form, and the risks will be in the hand of the patients. Even though the patient proposes the informed refusal, it does not break the relationship between the patients and doctors (Article 16 Paragraph (4) Health Minister Decree No. 290 of 2008).

From the description mentioned before, it can be seen that informed consent is very important because it raises the therapeutic contract between doctors and patients.

3.2 Philosophical Basis of Informed Consent and Informed Refusal in the Perspective of Common Law

One of the basic principals known in the Medical Law in the Common Law countries is that an adult patient with a sound mind should approve the medical action treated to him/her⁵. The reason why this approval is needed is related to the *bodily inviolability*.⁶ Medical action conducted to the patients is basically to invade the patient's sovereignty over his own body. Actually, the medical treatment can be justified as long as conducted for the patient's best medical interests.⁷

In the term of history, the concept of *informed consent* which is known today comes from the Common Law tradition. A court ruling in a dispute between *Mrs. Schloendorff v the New York Hospital 1914* was considered as the milestone of birth *informed consent* concept. The judge who tried the case, Justice Benjamin Cardozo, issued a statement which later becomes a reference in understanding informed consent law, especially in Common Law countries, as written below:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without patient's consent, commits an assault for which he is liable in damages." (Ny. *Schloendorff v the New York Hospital (1914)* 211 N.Y. 125, 105 N.E. 92).

The law construction of *informed consent* was adopted and developed from the concept that each individual has a right to decide all the things related to themselves. Generally, it has been understood that the decision making is by considering the aspects of benefits and risks. Therefore, before making a decision, we must have knowledge about its risk and benefit. Related to this case, the law gives protection to the individual who will give consent, by requiring someone who will receive the agreement to first submit all relevant information.⁸

⁵ Jackson, E. (2010). *Medical Law: Text, Cases, and Materials*. USA: Oxford University Press. p. 216-217.

⁶ Stauch, M. et al. (2002). *Sourcebook on Medical Law*. London. Cavendish Publishing. p. 103.

⁷ *Ibid.* p. 3-4.

⁸ Merz, J.F. *An Empirical Analysis of the Medical Informed Consent Doctrine: Search for a "Standard" of Disclosure*.

The patients have a full right to decide what should or shouldn't be conducted to their body and to get the information before being treated with the medical procedure or surgery. No one has the right to force the patient to undergo certain treatment. Even the doctor, can only act as a facilitator in the process of patient's decision making (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2840885/>).

The main aim of the *informed consent*, as stated by Nancy M. Kettle, is to protect the human rights and dignity. *Informed consent* is needed to guarantee the protection of *the right to privacy and bodily integrity*. In the context of medical service, this right is developed into *the right of self-determination*. In bio-ethical studies, the right of self-determination is based on the *principle of autonomy*.⁹

Related to this case, Nadia N. Sawicki¹⁰ explained the meaning of autonomy as follow: "Autonomy is a principle of self-governance that recognizes a person's right to make choices that further her sense of identity without undue interference or coercion by third parties. Autonomy is understood to be a non-consequentialist good – that is, autonomous decisions are valuable not necessarily because they reach the "right" result, but because they are our own."

It is also stated that the right to choose and to know the action procedure is a fundamental thing to the patients. Informed consent is a way to provide the information needed by the patient to help them in deciding.¹¹ Appropriately, the doctors should provide the informed consent seriously because it proves that the patient does not feel cheated or forced into the action conducted to him.¹²

The informed consent reflects a belief that every individual has the right to be free from any kinds of undesired interventions on his own body. In addition, it also reflects a moral principle that it is not right to force others people to do something that is contrary to his own will.¹³

Lord Steyn in the case of *Chester v Afshar* explain that the provisions which prohibit doctors to do the medical action (especially surgery) without the patient's consent have two objectives; to avoid the risk of injury which the patients are not ready to bear and as well as to respect the rights of patient autonomy and honor.¹⁴ Meanwhile, Lord Donaldson (*Re W* [1992] 4 All ER 627, 633) explained that the consent has two different functions in the context of a doctor-patient relationship. The first (called legal function), is to give justification of the medical actions which will be conducted. Without this kind of approval, the health worker who treated the patient would be considered committing acts that violate the law. Other function (called as a clinical function), is to to maintain patient's trust and cooperation (*Sidaway v. Bethlem RHG* [1985] 1 All ER 643).

Based on the above explanation, the philosophical bases of the informed consent, in the Common Law perspective, are among other: (1) to maintain the patient's physical safety; (2) to honor the right of patient's autonomy to decide all the things related to

⁹ Kettle, N.M. "Informed Consent: Its Origins, Purpose, Problems, and Limits", Graduate Thesis, Gainesville: School of Law, University of Florida, unpublished.

¹⁰ Sawicki, N.N. (2017). "Informed Consent as Societal Stewardship". *The Journal of Law, Medicine, and Ethics*, Volume 45.

¹¹ Parmar, P et al. (2016). "Consent in Medical Practice: Perceptions of Patients towards Legal Aspects of Informed Consent", *International Archives of Integrated Medicine*, Volume 13 Issue 4 April.

¹² O'Neal, O. "Some Limits of Informed Consent". *Journal of Medical Ethics*.

¹³ Furrow, B.R, et all. (1991). *Health Law: Cases, Materials, and Problems*, 2nd Ed, St. Paul: West Publishing Co. p. 321.

¹⁴ Herring, J. (2010). *Medical Law and Ethics*, 3rd Ed, New York: Oxford University Press. p. 146.

himself; (3) to give a justification of the medical treatment conducted by the health provider; and (4) to maintain the patient's trust and cooperation.

3.3. Philosophical Basis of Informed Consent and the Rejection of Medical Actions in Islamic Perspectives

The honor for the rights of patient's autonomy is the philosophical basis of informed consent. It also has a reference to the religious culture and teachings. For the Muslim patients, the implementation of autonomy right which is absolute such as in the west society is still very rare. There is a responsibility to the God, and he is in a coherent social life where the role of religious leaders is strong enough to influence the attitude of his life. Therefore, the implementation of autonomy right is also as a manifestation of the religious belief. Related to that case, Del Pozo and Fins explained that *informed consent* is an individual right as it is understood that Islamic Law honors the privacy of blood, property, and family.¹⁵

Zulham captured informed consent with the *Amanah* concept. According to him, there are *Amanah* dimensions related to the implementation of informed consent, namely: (1) Allah gives *Amanah* (trust) to the doctor to try hard to treat patients; (2) On the other side, Allah also gives *Amanah* to the patients to maintain their health and life; (3) Patient asks the doctor for a help to cure his disease and the doctor, then, explains various relevant things including medical treatment with its risk to the patients. If the patients approved, the informed consent is a trust *Amanah* to the doctor.¹⁶

Based on the explanation above, in the Islamic Law perspective, the philosophical bases of the Informed Consent are: (1) The respect to the privacy and blood, property and family; (2) The *Amanah* (the trust) from Allah to the doctors to really try to treat the patient and on the other side, *Amanah* for the patients to maintain their life and health.

3.4. Philosophical Basis of The Documentation of Medical Information into the Medical Records

Medical Records has a long story. In various literature, it is stated that the practice of medical record had been conducted since 25.000 BC, marked by the finding found by archaeologists of various ancient relics, the paintings on the procedure of medical practice, among others, about the amputation of the fingers that are now on the stone cave wall in Spain (originating from the paleolithic era). Furthermore, various kinds of medical Papyrus relics from Ancient Egypt, Edwin Smith Papyrus 2.000 BC, also showed that with the rise of human civilization, the medical information recording techniques also increases.¹⁷

Nowadays, the electronic tools with high technology such as a computer, microfilm, etc. are used to record the medical information. Seeing the medical development since the ancient times up to now, it can be said that the history of the medical record goes along with the history of medical science.

¹⁵ Packer, S. "Informed Consent with a Focus on Islamic Views", diunduh dari: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3516121/pdf/jima-43-3-9040.pdf>. [Accessed August 15, 2018].

¹⁶ Zulham. "The Concept of Amanah in Informed Consent", diunduh dari: <http://journal.uinjkt.ac.id/index.php/ahkam/article/viewFile/1240/1108>. [Accessed August 15, 2018].

¹⁷ Hatta, G.R. (2008). *Rekam Medis*. Jakarta: FKUI. p. 19.

In the past, the problem of medical records was not so noticed. The activity of medical recording in a doctor's office by using a Patient Card or hospital records that were formerly referred to, used to and called as "Status" was commonly done. However, it has not yet come up with legal problems. Moreover, its interests were not so felt because it could be said that there were almost zero lawsuits made against doctors or hospitals in Indonesia.¹⁸

However, the situation and condition are gradually changing. The rapid development of science and technology, the percentage of the increasing population growth and the symptoms of materialism and hedonism, all of which affect the way people think, including patients. It causes shifting relationships between doctors and patients; the former is a paternalistic relationship which is shifting towards impersonal transactional. The patient does not hesitate to sue the doctor or hospital considered negligent.¹⁹

Based on this point, the law must regulate the making of the medical record. Juridically, the regulation of medical record is in the *Permenkes RI Nomor 749a/MENKES/PER/XII/1989* (The Regulation of the Minister of Health of the Republic of Indonesia). This regulation is based on the Law Number 23 of 1992 concerning Health. However, based on the legal principle of *lex posteriori derogat legi priori*, the old regulation was declared null and void. The next legal basis is Article 46 and Article 47 of Law No. 29 of 2004 concerning Medical Practice, Article 29 paragraph (1) letter h of Law No. 44 of 2009 concerning Hospitals, and Minister of Health Regulation No.269 / Menkes / PER / III / 2008 concerning Medical Records.

1. Laws No. 29 of 2004 concerning Medical Practice

Article 46 Paragraph (1): Every doctor or dentist in conducting medical practice must make a medical record.

Article 46 Paragraph (2): The medical record as stated in paragraph (1) must be completed immediately after the patient has finished receiving health services. Every medical record must be given the name, time, and signature of the health provider who provides the service or treatment.

Article 47 Paragraph (1): The medical record document, as referred to in Article 46, is the property of a doctor, dentist, or healthcare facility, while the contents of the medical record belong to the patient.

Article 47 Paragraph (2): Medical record, as referred to in Paragraph (1) must be kept and kept confidential by the doctor or dentist and the leader of the health facilities

Article 47 Paragraph (3): The provisions regarding medical records include Paragraph (1) and paragraph (2) by Ministerial Regulation.

2. Law No. 44 of 2009 concerning Hospitals

¹⁸ Guwandi. (2005). *Rahasia Medis*. Jakarta: FKUI. p. 51.

¹⁹ *Ibid*. p. 52

Article 29 Paragraph (1) letter h: Every hospital has an obligation to carry out medical record.

3. Minister of Health Regulation No.269/Menkes/PER/III/2008. The content of this regulation would be discussed in a separate sub-chapter.

Juridically, since the enactment of the regulations mentioned above, the implementation of medical records by making patient data records is a legal obligation for doctors. In lawsuit cases or medical malpractice claims, medical records play an important role as evidence. The number of insurance companies in the health sector, the number of foreign tourists, and foreign investment in Indonesia increase the international relations, accreditation, and quality assurance. Thus, the doctor must get used to making complete records of the patient's medical data. Hospital through its organizational structure must give more attention to the implementation of well medical record.

It should be conducted because a medical record which is neatly organized, chronologically well and complete will be strong evidence in the court. Note in the medical record must also be clear that the writing can be read again by others. Without these conditions being fulfilled, a doctor and a hospital will find it difficult to defend himself before a court in a medical malpractice suit.

Then, in the Article 50 Law No. 29 of 2004 concerning Medical Practice, it is decided that a doctor or dentist has a right to get legal protection as long as they conduct the medical practice based on the professional standards and standard operating procedures. Based on these provisions, a doctor or dentist or health provider and the patient (health receiver) are given legal protection in conducting their duties. Therefore, the implementation of the duties must be completed with the proves and these proves were obtained in the documents containing noted, patient's identity, patient's examination, patient's medication, treatment, and other services given to the patients. All of those are there in the medical record.

Therefore, it can be said that the philosophical base of the making of medical record is to give legal protection both for the health provider and the health receiver (patients).

4. Conclusion

Based on the research's result and the discussion, the conclusion is that the philosophical base of the Informed Consent, Informed Refusal and Documentation of Medical Information into the medical record is; to fulfill the human rights of patients in accordance with their dignity as human beings, to provide legal protection for the health providers in carrying out their work, and to maintain patient trust and cooperation. Meanwhile, in the Islamic Law perspective, the philosophical bases of the Informed Consent are; (1) respect for the privacy of blood, property, and family; (2) God's mandate to the doctors to truly try to treat the patients and mandate to the patients to maintain their health and life. The documentation of the medical information into the medical record is to give legal protection in the form of a strong prove both for the health provider and health receiver if there is a medical dispute.

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