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JURIDICAL ANALYSIS OF E-CONSENT SERVICES BASED ON LAW NUMBER 17 OF 2023 ON HEALTH AT ZAINAL ABIDIN HOSPITAL, PAGAR ALAM, WAY KANAN

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Article

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Abstract

The development of information technology in the health sector has significantly changed how health services are delivered and regulated. One important change is the shift from conventional informed consent (oral or written) to e-consent or electronic technology-based consent. According to Article 335 of Law No. 17 Year 2023 on Health. Informed consent is a key element in ethical and legal medical practice. The main principle is the individual must give that consent. Based on Article 2 paragraph (1) Permenkes RI Number 290 /Menkes / Per / III / 2008 concerning Medical Action Consent states that "All actions that will be carried out on patients must obtain consent", therefore the article aims to analyze the rules for implementing e-consent and the obstacles to the application of e-consent in health services, especially at the Hospital Rsud Zainal Abidin Pagar Alam Way Kanan. This research method uses normative Judicial legal research. The results showed that the rules for e-consent have been regulated in Indonesian legislation, but the use of e-consent has weaknesses, such as patients, doctors, and other medical personnel not being accustomed to changes from conventional to digitalization. In addition, inadequate equipment from the Hospital is also an obstacle to implementing this E-consent service. The proposed suggestion is the need for improvement and training regarding the rules and work practice training related to e-consent between doctors, medical personnel, and patients at Zainal Pagar Alam Way Kanan Hospital.

A. INTRODUCTION

Health is one of life's most important needs in upholding daily activities. Humans make various efforts to realize a healthy life. Article 47 of Law Number 36 of 2009 stipulated that health efforts are organized in the form of activities with a promotive, preventive, curative, and rehabilitative approach that is carried out in an integrated, comprehensive, and sustainable manner. The development of the world of health is very rapid not only regarding diseases, but also disease management technology and supporting facilities that are increasingly modern and sophisticated.

The rights and responsibilities of patients concerning forthcoming actions by hospitals, particularly by doctors, are commonly known as informed consent. This process involves supplying potential participants with adequate information about a study, enabling them to make an informed choice regarding their voluntary involvement. Informed consent should encompass a procedure that aids the participant's comprehension of the information and allows ample opportunity for questions and reflection on their decision to participate. There is a growing interest in the research community in utilizing electronic media to enhance or replace traditional paper-based informed consent procedures. Electronic Informed Consent (EIC) can deliver information typically found in written consent documents, assess the participant's understanding of this information, and record their consent or that of their legally authorized representative (LAR). An electronic approach for obtaining informed consent may feature an interactive interface that improves participants' retention and understanding of the information provided. Furthermore, this electronic method enables quick updates to participants regarding any changes in informed consent that might influence their decision to continue their participation. Remote informed consent processes can still be executed using paper materials or electronically accessible documents when EIC methods cannot be implemented due to time constraints or technological challenges.

In essence, informed consent is a communication process that occurs between a doctor and a patient regarding the approval of a medical action that the doctor will perform on his patient.[1] The implementation of medical actions must obtain the patient's or his family's consent, manifested in the form of an informed consent document.[2] Permenkes RI Number 290 / MENKES / PER / III / 2008 concerning Medical Action Approval and Article 45 of Law Number 29 of 2004 concerning Medical Practice also explains the obligation to provide Informed Consent. Informed consent is necessary because of the Therapeutic Agreement. Each party certainly has its own rights and obligations that need to be respected, where everyone's right to receive will certainly intersect with the obligation to give.[3] Therefore, it can be concluded that Informed Consent is an agreement or permission given by the patient or family to the doctor who will carry out medical action against him. This is given after the patient or patient's family is given complete information or explanation about the action to be taken.

The application of electronic informed consent in Indonesia is still in the development and implementation stage.[4] Some hospitals have started digitizing informed consent forms to support the electronic medical record system (RME). The implementation of informed consent in Indonesia shows variations in the level of completeness of its filling. For example, the

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[1] Achmad Burso, "Aspek Hukum Persetujuan Tindakan Medis (Inform Consent)," *Law & Justice Journal* 1, no. 1 (2018): 1–18.

[2] Azrul Azwar, *Pengantar Pelayanan Dokter Keluarga* (Jakarta: Yayasan Penerbit Ikatan Dokter Indonesia, 2006).

[3] Safinatunnisa Boang Manalu, "Fungsi Informed Consent Dalam Pelaksanaan Perjanjian Terapeutik Antara Pasien Dengan Pihak Klinik (Studi Pada Klinik Jemadi Medan)," *Jurnal Civil Law USU* 1, no. 3 (2017): 1–15.

[4] Delfina Darianti, Vina Ervina Destiana Dewi, and Leni Herfiyanti, "Implementasi Digitalisasi Rekam Medis Dalam Menunjang Pelaksanaan Electronic Medical Record Rs Cicendo," *Jurnal Ilmiah Manusia Dan Kesehatan* 4, no. 3 (2021): 403–11, https://doi.org/10.31850/makes.v4i3.975.

results of research that has been carried out at Pertamina Bintang Amin Hospital Bandar Lampung by conducting observations and documentation studies of inpatient medical record files that have informed consent sheets for the period December 2018, it is known that out of 100 file samples, researchers analyzed the completeness of filling in the informed consent sheet based on the components of Identification Analysis (identity), Important reports, and Authentication (signature).[5] Another study at Pertamina Central Hospital Jakarta showed that 73% of informed consent forms were fully completed, while the remaining 27% were incomplete.[6] Hermina Arcamanik Hospital has been using the RME system since 2022 but still faces challenges in digitizing some forms, including informed consent. In March 2024, analysis showed that of the three informed consent forms, only 75% were successfully digitized, while the other 25% were still using manual methods.[7]

In transitioning from manual to electronic medical records, hospitals in Indonesia have digitized medical records. Medical record digitization is the stage of converting medical record documents from manual paper format to digital documents. This digitization aims to facilitate the management and exchange of medical information electronically and improve the efficiency of storage and access to medical data. Medical records are one of the indicators used to assess the quality of service in hospitals and impact patient satisfaction. Along with time and technology development, medical records have evolved from manual to electronic medical records. According to the Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022, electronic medical records are defined as medical records designed by implementing an electronic system. All health facilities must implement electronic medical records no later than December 31, 2023.

Based on the data above, the application of e-consent is not immediately well implemented in the process of switching from manual to electronic medical records. Medical record digitization is the stage of converting medical record documents from manual paper format to digital documents in the form of files such as PDF or JPG. This is done using a scanner scan. This digitization aims to facilitate the management and exchange of medical information electronically and improve the efficiency of medical data storage and access.

This research intends to discuss and examine in depth the regulations regarding electronic informed consent as well as procedures and obstacles in hospitals in Indonesia, especially Zainal Abidin Pagar Alam Hospital.

B. RESEARCH METHODS

This research uses normative juridical research methods, namely research that prioritizes secondary data. Normative juridical research uses literature studies or secondary data by studying books, legal journals, research results, theories, concepts, legal principles, and existing laws and regulations. The approaches used in this legal research are statutory approaches and historical approaches. The statutory approach is carried out by analyzing laws and regulations relating to legal issues. Legislation relating to legal issues. The historical approach is an approach that is carried out by looking at the background of the problem being studied and the development of the order related to the problems that occur in society.

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[5] Mardheni Wulandari et al., "Analisis Kelengkapan Pengisian Informed Consent Tindakan Beedah Di Rumah Sakit Pertamina Bintang Amin Tahun 2018," *Jurnal Ilmu Kedokteran Dan Kesehatan* 6, no. 2 (2019): 98–104, https://doi.org/10.33024/jikk.v6i2.2296.

[6] Jonathan Wicaksono, Sustin Farlinda, and Thomas M. Purba Purba, "Analisis Kelengkapan Pengisian Formulir Informed Consent Pada Pasien Rawat Inap Di RS Pusat Pertamina," *Jurnal Rekam Medik & Manajemen Informasi Kesehatan* 1, no. 1 (2022): 56–63, https://doi.org/10.47134/rmik.v1i1.17.

[7] Fasha Sabila Fitriani and Annisa Ulfah, "ANALISIS DIGITALISASI FORMULIR INFORMED CONSENT PASIEN ICU DALAM MENUNJANG REKAM MEDIS ELEKTRONIK DI RSU HERMINA ARCAMANIK," *PREPOTIF : Jurnal Kesehatan Masyarakat* 8, no. 2 (2024): 3699–3703.

C. ANALYSIS AND DISCUSSION

1. Terms and Procedures of E-Consent Services at Zainal Abidin Pagar Alam Regional General Hospital Way Kanan Based on Law Number 17 of 2023 Concerning Health

Every patient has the right to determine what treatment procedures they will undergo, including the risks that must be borne due to certain treatment methods. However, patients also have the right to know whether other alternatives exist, including risks. There are also those who argue that patients have the right to know things that are outside the scope of health but related, for example, social factors.

Implementing medical actions must obtain the patient's or his family's consent, manifested in the form of an informed consent document.[8] Informed Consent is an agreement to a medical action performed by a doctor on a patient. This approval can be done orally or in writing. In essence, informed consent is a communication process that occurs between a doctor and a patient regarding the approval of a medical action that the doctor will take against his patient.[9] In Permenkes RI Number 290 / MENKES / PER / III / 2008 concerning Medical Action Approval and Article 45 of Law Number 29 of 2004 concerning Medical Practice also explains the obligation to provide Informed Consent. Informed consent is necessary because of the Therapeutic Agreement. Each party certainly has its own rights and obligations that need to be respected, where everyone's right to receive what they have will certainly intersect with the obligation to give informed consent.[10] Therefore, it can be concluded that Informed Consent is an agreement or permission given by the patient or family to the doctor who will carry out medical action against him. This is given after the patient or patient's family is given complete information or explanation about the action to be taken.

Based on Article 293, paragraphs (6) and (7) of Law Number 17 of 2023 concerning Health that consent is given by the patient concerned if the patient is incapable of giving consent, then the approval of the action can be given by the representative. Based on Article 1 point (7) Permenkes RI Number 290 / MENKES / PER / III / 2008 concerning Approval of Medical Action explains that patients who are said to be competent are:

a. According to laws and regulations, the patient is an adult or not a child.
b. Unimpaired physical awareness;
c. Able to communicate reasonably.
d. No mental retardation and no mental illness to be able to make decisions freely.

A competent person must give informed consent. If the person giving consent is not a qualified person, then the doctor is obliged to refuse. Because informed consent is the basis for a doctor to perform or carry out medical action against his patient. Informed consent must be an agreement which contains the patient's consent to the medical action that the doctor will take.

The implementation of informed by doctors must be based on clear procedures. In carrying out this procedure, before taking medical action on a patient, a doctor must pay attention to several things, namely:

a. Timing of Provision of Medical Information and Consent

The timing of providing medical information and consent is an essential issue in health services related to optional actions, not emergencies. Based on Decree

[8] Azwar, *Pengantar Pelayanan Dokter Keluarga*.
[9] Burso, "Aspek Hukum Persetujuan Tindakan Medis (Inform Consent)."
[10] Manalu, "Fungsi Informed Consent Dalam Pelaksanaan Perjanjian Terapeutik Antara Pasien Dengan Pihak Klinik (Studi Pada Klinik Jemadi Medan).".

HK.00.06.3.5. 1866/1999, requires the patient to consent no later than 24 hours. This means that (under normal circumstances) medical information should have been provided more than 24 hours (at least 36 hours before the scheduled action), so the patient still has 12 hours of thinking time to determine whether the doctor's offer/proposal is approved or rejected.

b. Place of Information Provision

According to Kep.Dir.Yanmedis HK.00.06.3.5. 1866/1999, medical information must be delivered in a doctor's office or another appropriate setting that ensures privacy and minimizes interruptions from others. This is crucial for ensuring patients and their families receive accurate information. Given the various locations where medical information may be shared, hospitals are required to designate specific areas or rooms for this purpose. When hospitals create such spaces, it facilitates a smooth process, enhancing the quality of informed consent services. This requirement is further reinforced by Permenkes No.290/2008, particularly in article 17 (2), which states that healthcare facilities are accountable for obtaining consent for medical procedures. Additionally, Article 18 (2) highlights the need for the health department to oversee these services to improve the overall quality of healthcare delivery.

c. Medical Information Filling

Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999. Not yet compliant. In this regulation, there are six things/medical information that must be explained to the patient/family:

1) Objectives and prospects of success of the medical action to be performed (purpose of medical procedure),
2) The procedure for medical treatment to be performed (contemplated medical procedures),
3) Risk (risk inherent in such medical procedures).
4) Other available medical alternatives and their respective risks (alternative medical procedure and risk),
5) Prognosis of the disease if the medical procedure is performed (prognosis with and without medical procedure).
6) Diagnosis.

d. The language used in the Informed Consent

The use of language by doctors in explaining medical action plans to patients/families is essential because of differences in the knowledge of doctors and patients/families regarding the material that must be explained to patients, usually medical terms, and differences in social status, doctor's time availability, quite a lot of workload, can result in less effective communication. This is in line with Astuti's opinion that providing information using medical language will not bring any results, instead it will confuse patients. Therefore, information provided by doctors to their patients should be conveyed in simple language and easily understood by patients. It is known that most patients are unfamiliar with the language of medicine and not all medical terms can be translated easily into the language of lay people. It would be better if simple pictures accompanied the explanation so the patient / family would quickly understand it.

e. Provide an opportunity to ask questions.

Before a patient/family decides to continue treatment or even seek other services, one of them is determined by the process of providing medical information. This process takes time to determine whether to accept or reject the doctor's offer. Here there must be a dialog between the doctor and the patient/family. This dialog is to obtain a thorough understanding so that the decision becomes unanimous. Based on this understanding, the patient sets an independent decision according to the consideration that is best for him (adequate decision).

f. Provide medical information related to the implementation of the action.

The Permenkes provide flexibility in the delivery of explanations. If the treating doctor/dentist is absent, the explanation may be delegated to another competent doctor (Article 10(2)). In addition to the doctor/dentist, other health personnel directly involved in the treatment may also provide explanations. If one of the team of doctors is absent in certain circumstances, the task of explanation can be delegated to another health worker who is directly involved in the treatment (Article 10 (4)). There is no explanation as to who is meant by other health personnel. However, the author suspects that it refers to nursing staff. If that is the case, then the delegation of authority is only justified if the medical procedure is not a surgical or other invasive, high-risk procedure. The nurse who gets the task must have sufficient knowledge and experience so that what is explained is not too different from what the doctor/dentist in charge explains. This provision was implemented by one of the hospitals studied, which implemented this policy on a limited basis. The designated nurse is a senior nurse who represents the hospital leader in the absence of the leader/doctor. This is usually done during holidays or non-working hours.

g. Providing Written Medical Information

The results of the above study would align with the health ministry's policy. Based on Permenkes 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999, the way of delivering an explanation by the doctor in charge is differentiated upon

1) verbally delivered explanations,
2) explanations submitted in writing.

This provision allows doctors to choose whether only to deliver orally or both are carried out. According to the results of the assessment, there were no doctors who provided explanations in writing and explained orally. However, this result concludes that informants agree that if information is explained, it should be written first and then explained orally. Written and verbally explained information will be easier to understand and can be reread. Written information will provide information certainty and legal certainty because it can be proven authentically.

Oral information has various disadvantages. Firstly, the vagueness of medical information is weak as evidence, so written and verbally explained information will reduce this. It is implied that written information is better than oral information, and doctors can use aids, such as leaflets or other publications if they can help provide detailed information. Based on this explanation, it can be concluded that explanations with aids are expected to be more effective, especially if the information is in writing. It will certainly be easier to understand because it can be re-read.

Written information can be a good document to be used as strong evidence to protect interested parties. Therefore, it is necessary to review various policies that state that medical information is conveyed orally and written only as a complement.

Information should be submitted in writing and explained orally, not vice versa. The procedure for using the informed consent check is:

a. Own a laptop or tablet device;
b. Has a stable Internet Network;
c. Access the website page rsudzapa.check.teach;
d. Login with username and password;
e. Perform steps according to hospital duties.

2. Strengths and weaknesses of E-Consent Services at Zainal Abidin Regional General Hospital Pagar Alam Way Kanan Based on Law Number 17 of 2023 concerning Health.

Implementing medical actions between doctors and patients is a trust-based relationship. In the relationship between Doctors and Patients, it is said that basically, the relationship rests on 2 (two) fundamental individual rights, namely the right to information (The Right to Information) and the right to self-determination. (The Right of Self Determination). The Right to self-determination is a fundamental or primary individual right that can be interpreted as the right to privacy and one's own body. The Right to Information, or the Right to give consent, is referred to as "Informed Consent".

The provisions of the 1945 Constitution, regarding the right to self-determination, are regulated in the provisions of Article 28 A that every person has the right to life and the right to defend his life and life, while the provisions regarding the right to information are regulated in Article 28 F of the 1945 Constitution, that every person has the right to communicate and obtain information to develop his personal and social environment, and has the right to seek, obtain, own, store, process and convey information by using all available channels.[11]

The history of the relationship between doctors and patients that has been going on for a long time begins with a paternalistic vertical relationship pattern where the position of doctors and patients is not equal. Namely, the position of doctors is higher than patients because doctors are considered to know about everything related to illness and healing. In contrast, patients are considered to know nothing about illness and treatment.[12] This paternalistic vertical relationship pattern has positive and negative impacts. The positive impact is that it is very helpful for patients in terms of patients who are unfamiliar with their illnesses. Still, on the other hand, it also has a negative impact, namely the doctor's actions in the form of steps in seeking the patient's healing are doctor actions that limit the patient's autonomy. In the later stages of the period, along with the development of the dynamics and progress of society, there was a shift in the relationship between doctors and patients. The relationship between doctors and patients has shifted to a more egalitarian, equal, horizontal contractual relationship.

This pattern of horizontal contractual relationships gives rise to a horizontal legal aspect characterized by *inspanningverbintenis,* a legal relationship between two legal subjects, namely the patient and the doctor, who hold equal positions, resulting in rights and obligations for the parties involved. This legal relationship does not promise anything (such as recovery or death) because the object of this legal relationship is the maximum effort made with care and full responsibility by the doctor based on their knowledge and experience in treating the patient to cure their illness.[13]

[11] Soekidjo Notoatmodjo, *Etika Dan Hukum Kesehatan* (Jakarta: Rineka Cipta, 2010).
[12] Ardityo Purdianto Kristiawan, "Kedudukan Hukum Informed Consent Dalam Pemenuhan Hak Pasien Di Rumah Sakit," *Jurnal Hukum Dan Dinamika Masyarakat* 19, no. 1 (2021): 1–23.
[13] Syarifa Mahila, "Aspek Perdata Transaksi Terapeutik Dalam Hubungan Hukum Antara Dokter Dengan Pasien," *Jurnal Ilmiah Universitas Batanghari Jambi* 11, no. 1 (2011): 61–69.

Before the year 2000, there were only 7-13 malpractice reports to the MKEK. In the years 2000-2001, this number increased rapidly to 20-30 cases per year. The malpractice case that drew attention was the case of Dr. Ayu and colleagues, who the Supreme Court sentenced for causing the death of patient Sisca Makatey. During the trial, it was proven that before performing an emergency cesarean section on the victim, they did not inform the victim's family about the possible outcomes for the victim.[14]

The Department of Health website mentions that as of March 2011, the Indonesian Medical Disciplinary Honorary Council (MKDI) had handled 127 complaints of disciplinary violations committed by doctors or dentists. Of that number, about 80 percent were caused by a lack of communication between doctors and patients. When detailed by the field of expertise being complained about, the most common are general practitioners (48 cases), surgeons (33 cases), obstetricians and gynecologists (20 cases), pediatricians (11 cases), internists (10 cases), pulmonologists (4 cases), neurologists (4 cases), anesthesiologists (4 cases), ophthalmologists (3 cases), cardiologists (3 cases), radiologists (2 cases), and each 1 case by psychiatrists, ENT specialists, and dermatologists, as well as 10 dentists.[15]

Therefore, the role of the informed consent mechanism is often studied to what extent it can reduce malpractice claims caused by the knowledge gap between doctors and patients regarding the medical world, where the therapeutic transaction at this stage is not a commitment with a clear object (*resultaatverbintenis*), but rather a commitment with an object of effort/maximum result (*inspanningverbintenis*) because the patient's recovery rate is not only influenced by the doctor's ability but also by other factors beyond that.[16]

The consent form must be based on all elements of proper informed consent, namely knowledge and competence. Some hospitals and doctors have developed consent forms that summarize all information and also include permanent records, usually written in the patient's medical record. The patient must receive all information before the medical action plan is carried out. The provision of this information should be objective, impartial, and without pressure. After the patient receives all the information, they should be given time to think and decide. The doctor may not carry out the process of providing information and obtaining consent for medical procedures if the patient is in a critical emergency condition. In this condition, the doctor will prioritize actions to save the patient's life. However, the procedures for keeping the patient's life are still carried out according to service standards and high professionalism.[17]

Using E-consent has several advantages, such as time and cost efficiency, because it is not feasible to update informed consent constantly, which can be time-consuming and costly and even cause psychological fatigue in filling out manual informed consent forms. Patients are given the freedom to control their data while being provided with the latest news about who is using the samples, for what purpose, and what they intend to use them for in further research. This principle of transparency is only possible if using a digital format with centralized data that is constantly monitored and updated. In addition, the use of e-consent reduces the risk of document errors. It supports legal processes, meaning that this electronic e-consent system can reduce the likelihood of losing physical documents or information writing errors. Furthermore, this e-consent is stored digitally on servers, which can be used as valid legal evi-

[14] Wahyu Rizki Kartika Ilahi, "Resiko Medis Dan Kelalaian Medis Dalam Aspek Pertanggungjawaban Pidana," *Jurnal Hukum Volkgeist* 2, no. 2 (2018): 170–86, https://doi.org/10.35326/volkgeist.v2i2.109.

[15] "Dugaan Pelanggaran Disiplin Terbanyak Akibat Kurangnya Komunikasi Dokter Dan Pasien – Sehat Negeriku," accessed December 24, 2024, https://sehatnegeriku.kemkes.go.id/baca/rilis-media/20110521/451104/dugaan-pelanggaran-disiplin-terbanyak-akibat-kurangnya-komunikasi-dokter-dan-pasien/.

[16] Siska Armawati Sufa and Didik Sugeng Widiarto, "Malapraktik Dalam Tindak Tutur Kesehatan: Kajian Perspektif Komunikasi Antara Dokter Dengan Pasien," *Jurnal Riset Komunikasi* 1, no. 1 (2018): 14–21.

[17] Sang Gede Purnama, *Modul Etika Dan Hukum Kesehatan Informed Consent, Program Studi Kesehatan Masyarakat* (Bali: Fakultas Kedokteran Universitas Udayana, 2016).

dence following Law Number 1 of 2024, amending Law Number 11 of 2008 concerning Electronic Information and Transactions.

Digital formats provide better prospects for facilitating communication with patients through E-consent. However, this convenience must be accompanied by consistent application of informed consent process standards. The informed consent given to subjects must use language that is easy to understand and transparent.

However, using E-consent also has its drawbacks, such as Patients, Doctors, and other Medical Staff not being accustomed to the shift from conventional to digital. Therefore, they feel more hindered by the presence of this E-consent service. In addition, the inadequate equipment from the hospital has also become an obstacle to implementing the E-consent service. E-consent in its implementation at RSUD Zainal Abidin Pagar Alam faces infrastructure constraints that are inadequate due to its location in a district where infrastructure development is uneven and the level of technological literacy is still low, as patients, medical staff, and doctors are not yet accustomed to technology. This can hinder the e-consent process.

In addition to the issues above, implementing e-consent in Indonesia is still vulnerable to security risks. The lack of an independent cybersecurity system opens up opportunities for cyber attacks such as hacking and malware to easily infiltrate data related to patient information, medical personnel, and doctors.

D. CONCLUSION

A competent person must give informed consent. If the person giving consent is not qualified, the doctor is obliged to refuse. Because informed consent is the basis for a doctor to perform or carry out medical actions on their patient, informed consent must include approval, which contains the patient's consent to the medical actions the doctor will perform. In addition, rapid global development forces Indonesia to keep up with the changes, necessitating the accommodation of regulations, supporting infrastructure, and providing comprehensive education on the use of informed consent.

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