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Design and Development of a Web-Based Informed Consent Information System to Improve the Efficiency and Legal Compliance of Healthcare Administrative Services

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Abstract: This study aims to design a web-based Informed Consent Information System to improve administrative efficiency and support the legality of healthcare services. The research method used is the Waterfall method, encompassing the stages of requirements analysis, system design, implementation, testing, and maintenance. The resulting system is a web-based application featuring patient data management, physician data management, medical procedure data, electronic medical procedure consent forms, electronic signatures, as well as the printing of Informed Consent documents and reports. This system was designed as a solution to the problems identified through observations at Tk. II Dustira Hospital, where Informed Consent documents were still managed manually, resulting in inefficiencies in the storage, archiving, and retrieval processes. The system has proven capable of simplifying the management of medical procedure consent documents, improving the administrative efficiency of healthcare services, and supporting digital, structured, and easily accessible document storage whenever needed.

Keywords: *Informed Consent, Waterfall, Information System, Legality, Digitization.*

Indonesian Abstract: *Penelitian ini bertujuan merancang Sistem Informasi Informed Consent berbasis web guna meningkatkan efisiensi administrasi dan mendukung legalitas pelayanan kesehatan. Metode penelitian yang digunakan adalah metode Waterfall yang mencakup tahapan analisis kebutuhan, perancangan sistem, implementasi, pengujian, dan pemeliharaan. Sistem yang dihasilkan merupakan aplikasi berbasis web dengan fitur pengelolaan data pasien, data dokter, data tindakan medis, formulir persetujuan tindakan medis elektronik, tanda tangan elektronik, serta pencetakan dokumen Informed Consent dan laporan. Sistem ini dirancang sebagai solusi atas permasalahan yang ditemukan berdasarkan hasil observasi di Rumah Sakit Tk. II Dustira, yaitu pengelolaan dokumen Informed Consent yang masih dilakukan secara manual sehingga menimbulkan ketidakefisienan dalam proses penyimpanan, pengarsipan, dan pencarian dokumen. Sistem yang dirancang terbukti mampu mempermudah pengelolaan dokumen persetujuan tindakan*

medis, meningkatkan efisiensi administrasi pelayanan kesehatan, serta mendukung penyimpanan dokumen secara digital, terstruktur, dan mudah diakses kapan pun dibutuhkan.

Keywords: Informed Consent, Waterfall, Sistem Informasi, Legalitas, Digitalisasi

INTRODUCTION

The rapid advancement of information technology within the digital healthcare ecosystem has created significant opportunities to improve the efficiency of clinical administrative governance, one of which is through the implementation of Electronic Informed Consent (e-Consent) for medical procedures (Naurah & Simarmata, 2024). Fundamentally, informed consent represents an agreement between healthcare professionals and patients or their legal representatives after comprehensive information regarding the proposed medical intervention has been provided. This document serves not only as an administrative requirement but also as an ethical instrument that respects patient autonomy and dignity while functioning as a legal document that provides legal certainty for healthcare professionals and protects patients' rights to receive adequate medical information (Dewi et al., 2025). Furthermore, it serves as evidence that patients have received sufficient information to make informed decisions regarding their medical care (Winarti & Rizka, 2025).

From a legal perspective, the implementation of informed consent in Indonesia is supported by a comprehensive and integrated regulatory framework. Law Number 17 of 2023 concerning Health explicitly mandates patient consent prior to any medical intervention. The digital transformation of informed consent is further supported by Minister of Health Regulation Number 24 of 2022 concerning Medical Records, which requires the nationwide implementation of electronic medical records. Moreover, the authenticity of electronic documents and the legal validity of electronic signatures are guaranteed under Law Number 11 of 2008 concerning Electronic Information and Transactions (ITE Law). Collectively, these regulations establish a strong legal foundation for healthcare institutions to transform conventional paper-based consent documents into secure digital systems.

Despite this supportive regulatory framework, the management of informed consent forms in many healthcare facilities remains suboptimal because it continues to rely on conventional paper-based documentation. This manual archiving approach creates several systemic challenges, including a high risk of document loss or damage, increasing physical storage requirements, and lengthy document retrieval and retention processes. These issues were confirmed through field observations conducted at Dustira Military Hospital Level II, where retrieving informed consent documents required considerable time due to the absence of a structured digital archiving system. Such delays may weaken the legal reliability of medical documentation, which should be readily accessible for administrative purposes as well as legal evidence whenever required.

The benefits of digitalizing informed consent have been widely validated by previous studies. Internationally, Gesualdo et al. (2021), through a systematic review of 73 studies, concluded that the adoption of digital informed consent tools did not negatively affect clinical outcomes. Instead, interactive multimedia platforms significantly improved patients' understanding of medical information. Similarly, Parsons et al. (2023) demonstrated that digital informed consent platforms enhanced physician–patient communication while producing more systematic documentation of medical procedures. Within the Indonesian context, Jayanto et al. (2021) also reported that implementing electronic informed consent significantly improved administrative management and facilitated digital document retention in healthcare facilities.

Although research on informed consent continues to expand, existing system development approaches remain largely fragmented. Mundok et al. (2024) developed an informed consent application using the Waterfall methodology but did not address structured digital archiving or legal compliance. Likewise, Fitriani and Ulfah (2024) found that digitalization at Hermina Arcamanik General Hospital had not been fully implemented because authentication still relied on handwritten signatures requiring separate scanning processes. From a usability perspective, Ibrahim et al. (2025) designed an informed consent interface using the User-Centered Design (UCD) approach and achieved a user acceptance rate exceeding 90%; however, the design was not integrated into a comprehensive information system architecture. Meanwhile, Fajrin et al. (2025) employed the Agile methodology but focused exclusively on document completeness analysis without providing integrated modules for electronic form completion and digital archiving.

From the legal standpoint, Naurah and Simarmata (2024) emphasized that electronic informed consent is legally valid provided that it fulfills the principles of information transparency, patient comprehension, voluntary consent, and secure authentication mechanisms. This legal validity is reinforced by Nurandini and Suryani (2024), who argued that certified electronic signatures in electronic medical records possess legal force equivalent to conventional handwritten signatures under the Electronic Information and Transactions Law and Government Regulation Number 71 of 2019. A comprehensive review of the literature reveals a clear research gap: previous studies have generally focused either on legal analyses or on isolated technical modules of informed consent systems. To date, no study has comprehensively integrated patient data management, electronic consent form completion, digital signature authentication, and structured digital archiving into a unified web-based information system that simultaneously satisfies healthcare operational requirements and legal compliance.

Therefore, the novelty of this study lies in the design and development of a web-based Informed Consent Information System that integrates all functional components and legal compliance requirements within a single platform. Accordingly, this research aims to develop a system capable of improving the efficiency of healthcare administrative processes, ensuring secure document storage and rapid document retrieval, and strengthening the legal validity of medical records through a structured digital archiving management system.

METHODS

Research Design

This study employed a Research and Development (R&D) methodology with a qualitative approach to design and develop a web-based Informed Consent Information System aimed at improving the efficiency and legal compliance of healthcare administrative services. The qualitative approach was adopted to gain an in-depth understanding of the existing informed consent process and identify user requirements through direct observation and semi-structured interviews. The findings served as the foundation for designing the proposed information system.

Data Collection Techniques

The data required for system development were collected using the following techniques:

Observation

Direct observations were conducted to examine the existing informed consent management process, including document completion, storage, and retrieval procedures. This process enabled the identification of operational workflows, existing practices, and problems encountered in managing informed consent documents.

Interviews

Semi-structured interviews were conducted with medical record officers and healthcare professionals involved in the informed consent process. The interviews aimed to gather detailed information regarding user requirements, current workflow limitations, and expectations for the proposed web-based information system.

Literature Review

A comprehensive literature review was carried out by examining scientific journal articles, books, government regulations, and other relevant references related to informed consent, electronic medical records, healthcare information systems, digital signatures, and system development methodologies. The literature review provided both theoretical and regulatory foundations for the proposed system.

System Development Method

This research adopted the Waterfall model as the System Development Life Cycle (SDLC) framework because of its structured, sequential, and systematic development process. The Waterfall methodology consists of several consecutive phases, beginning with requirements analysis and continuing through system design, implementation, testing, and maintenance. This linear approach ensures that each phase is completed before proceeding to the next, thereby minimizing development errors and ensuring that the final system meets predefined user and organizational requirements.

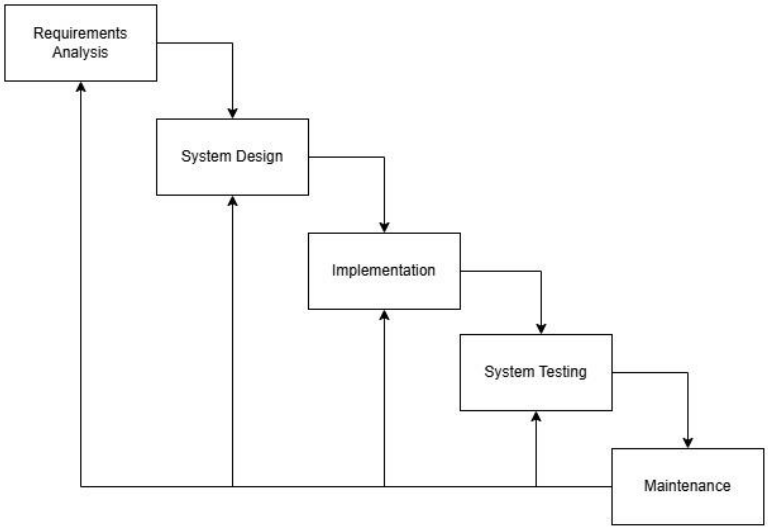


Figure 1. Waterfall Model

The stages of the Waterfall development model implemented in this study are described as follows:

Requirement Analysis

This initial phase involved identifying system requirements through observations and interviews to understand the current informed consent management process and determine user needs. Functional and non-functional system requirements were analyzed to establish the system specifications.

System Design

During this phase, the system architecture, database structure, business process workflows, and user interface (UI) were designed. Unified Modeling Language (UML) diagrams and database models were developed to represent system functionality and data relationships.

Implementation

The approved system design was implemented as a web-based application using PHP as the programming language and MySQL as the database management system. The developed application includes modules for patient management, physician management, medical procedure data, electronic informed consent forms, digital signature authentication, and consent document generation and printing.

System Testing

The completed system was tested to verify that all functional requirements were correctly implemented and operated according to user expectations. Testing ensured that each module functioned properly and produced accurate outputs.

System Maintenance

The final phase involved correcting errors identified after deployment and performing system improvements based on user feedback and evolving organizational requirements to ensure long-term system reliability and usability.

RESULTS AND DISCUSSION

System Analysis and Design

System Flowmap

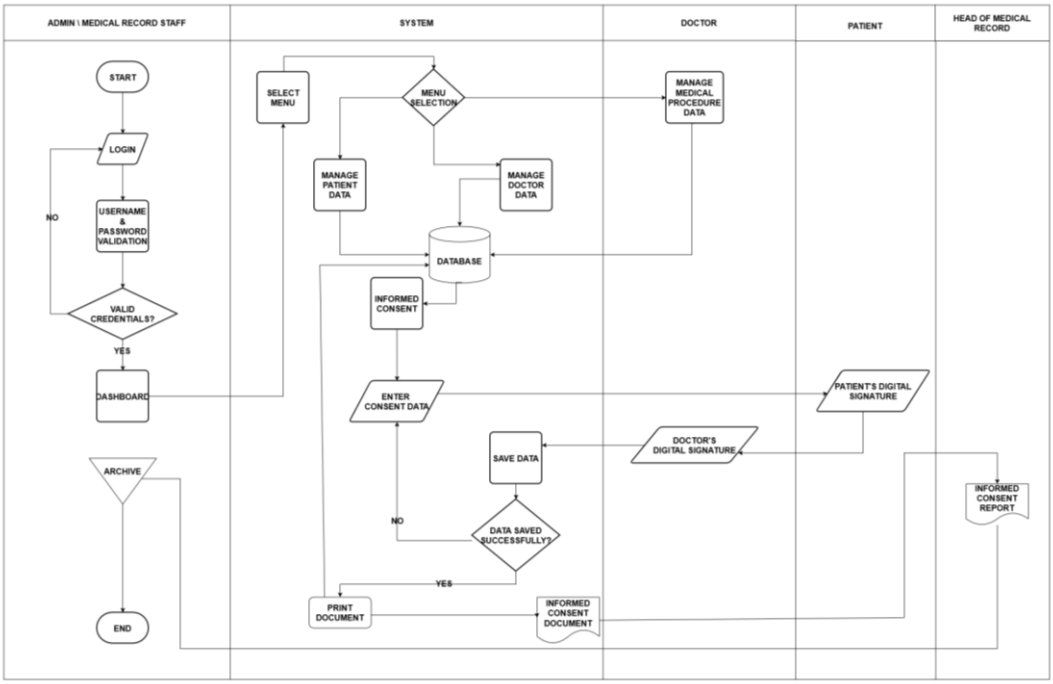


Figure 2. Flowmap of the Informed Consent Information System

The proposed informed consent information system flowmap illustrates the sequence of procedures and the controlled flow of data among system entities in a systematic manner. The process begins with user authentication, where authorized staff log into the system and their credentials are validated to grant access to the dashboard for managing master data stored in

the database. The workflow then proceeds with the entry of informed consent data by the staff, followed by the application of encrypted electronic signatures from both the patient and the physician. The system incorporates a data retention validation mechanism, whereby unsuccessful data storage triggers a return to the data entry stage for correction, while successful storage results in the generation of a printable informed consent document. The stored data also serve as the basis for generating informed consent reports used by the Head of the Medical Records Department for monitoring and administrative purposes.

Context Diagram

Figure 3 illustrates the context diagram of the proposed web-based Informed Consent Information System, which involves four external entities: the Administrator/Medical Records Officer, Physician, Patient, and Head of the Medical Records Department. The Administrator/Medical Records Officer manages master data, records informed consent information, verifies patient data, and generates informed consent documents. The Physician reviews the patient's medical information and provides electronic approval through a digital signature. The Patient supplies personal information and gives consent for the proposed medical procedure by signing the informed consent electronically. Meanwhile, the Head of the Medical Records Department receives and reviews informed consent reports generated by the system for monitoring, evaluation, and administrative purposes. The system functions as the central processing unit that facilitates secure data exchange among all external entities while ensuring data integrity, confidentiality, and efficient management of informed consent records.

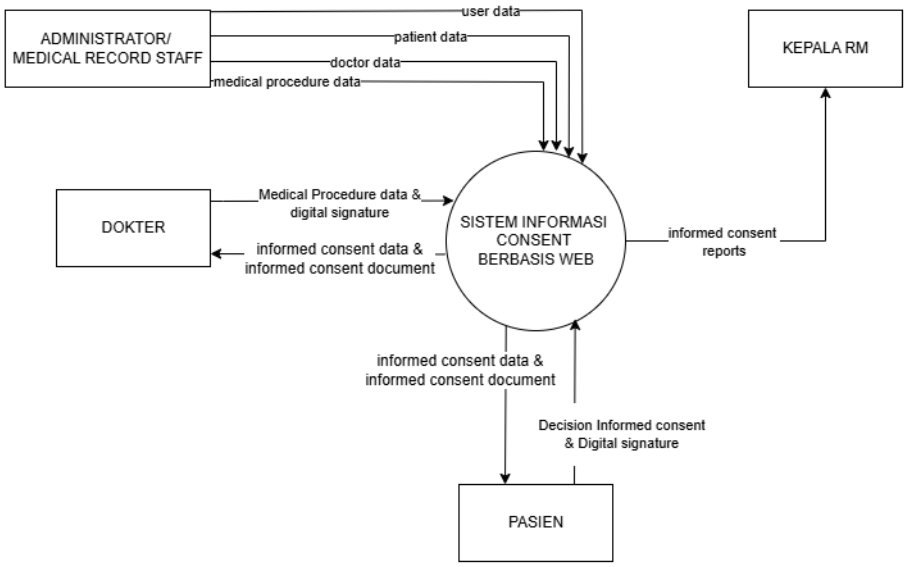


Figure 3. Context Diagram of the Web-Based Informed Consent Information System

Data Flow Diagram (DFD)

The Level 1 Data Flow Diagram (DFD) of the proposed web-based Informed Consent Information System provides a detailed representation of data processing and information flow through six integrated processes. The workflow begins with the management of patient master data (Process 1.0) and physician master data (Process 2.0), where the Administrator/Medical Records Officer enters and maintains the respective records in the

patient and physician databases. These databases subsequently serve as reference sources for physicians when recording medical procedure information (Process 3.0).

The process then continues with informed consent completion (Process 4.0), during which the patient reviews the proposed medical procedure, provides consent, and signs the informed consent electronically, while the physician also validates the document with an electronic signature. Once all required information has been verified, the system performs data storage and retention (Process 5.0) by securely saving the informed consent record into the database to ensure data integrity, confidentiality, and long-term availability. Finally, the system executes report generation (Process 6.0) by retrieving stored informed consent records and producing comprehensive informed consent reports requested by the Head of the Medical Records Department. These reports support administrative monitoring, legal documentation, and evaluation activities. Through these interconnected processes, the proposed system enables a fully electronic, structured, and secure management of informed consent documentation while improving data accessibility, operational efficiency, and the reliability of medical record management.

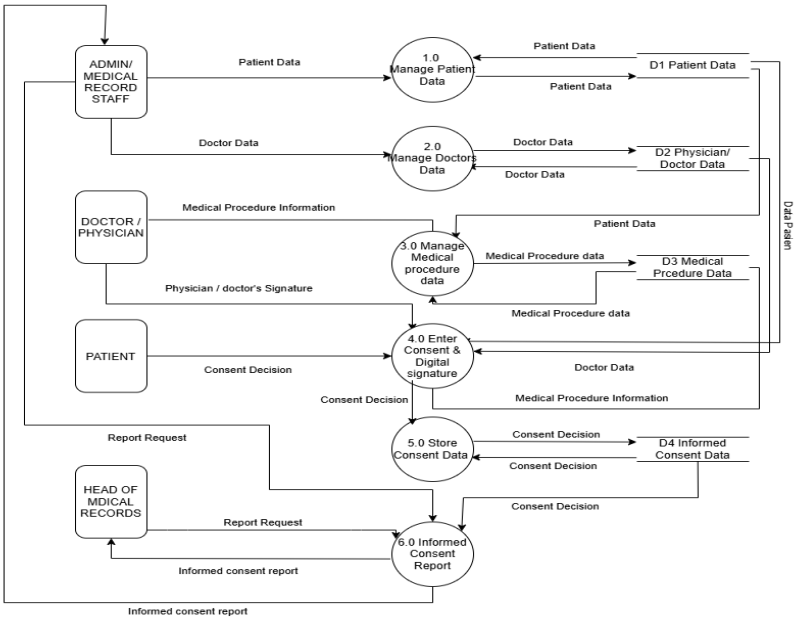


Figure 4. Data Flow Diagram (DFD) of the Informed Consent Information System

Entity Relationship Diagram (ERD)

Figure 5 presents the Entity Relationship Diagram (ERD) of the proposed web-based Informed Consent Information System, illustrating the logical structure of the database and the relationships among its core entities. The system consists of five primary entities: User, Patient Data, Physician Data, Medical Procedure Data, and Informed Consent. The User entity stores authentication and authorization information for system administrators and authorized personnel. The Patient Data entity maintains demographic and identification information required for documenting informed consent, while the Physician Data entity contains healthcare provider information associated with the medical procedures. The Medical Procedure Data entity records details of the proposed medical interventions, including diagnoses, procedures, and relevant clinical information provided by physicians.

The Informed Consent entity serves as the central transactional table that links patient records, physician records, and medical procedure information while storing consent details, electronic signatures, approval status, and the date and time of authorization.

The relationships among these entities ensure data integrity and consistency by enabling seamless integration throughout the informed consent process. This relational database design supports efficient data retrieval, minimizes data redundancy through normalization, and facilitates secure documentation of medical information. Consequently, the system provides a structured and reliable platform for managing patient information, recording medical procedures, obtaining informed consent electronically, and generating legally valid documentation within the medical records management system.

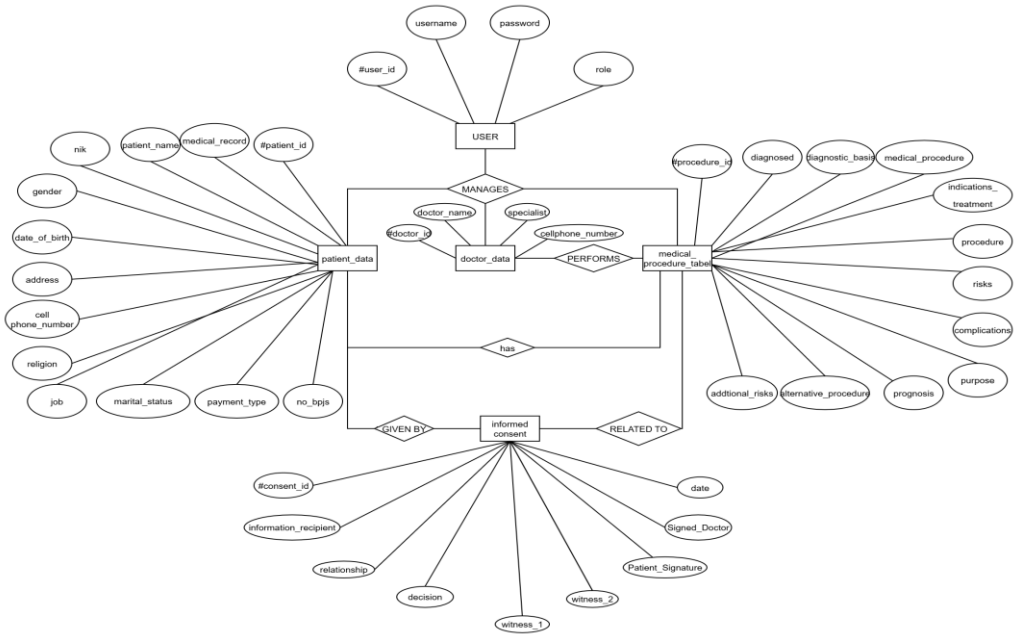


Figure 5. Entity Relationship Diagram (ERD) of the Informed Consent Information System

System Implementation

Login Page

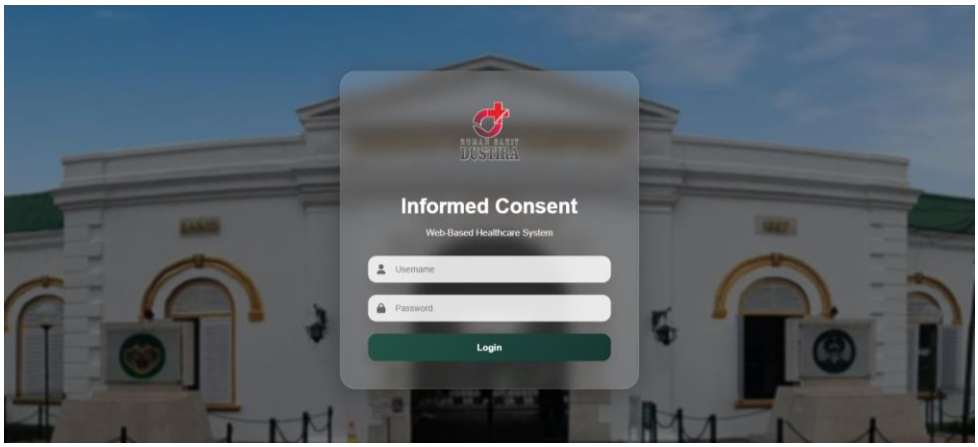


Figure 6. Login Form

Figure 6 presents the login form, which serves as the initial access page for medical records officers, physicians, and the Head of the Medical Records Department. Users are required to enter a valid username and password before accessing the system. Once the credentials are successfully verified, the system redirects the user to the dashboard according to the assigned user role and access privileges.

Dashboard Page

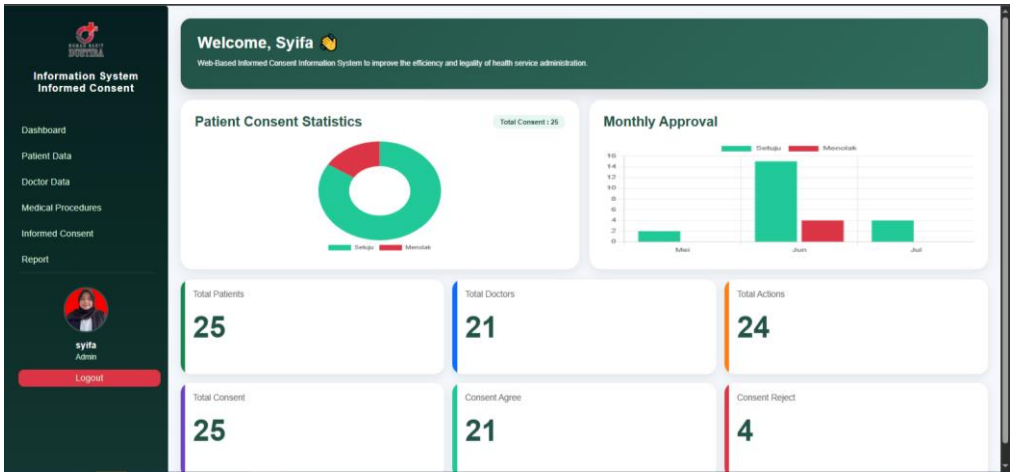


Figure 7. Dashboard Page

Figure 7 illustrates the dashboard page displayed after the user successfully enters a valid username and password. This page functions as the main navigation interface for accessing the various features available in the system. The dashboard provides access to patient data, physician data, medical procedure data, informed consent records, and informed consent document reports. The menus displayed may vary depending on the role and authorization level of each user.

Patient Data Page

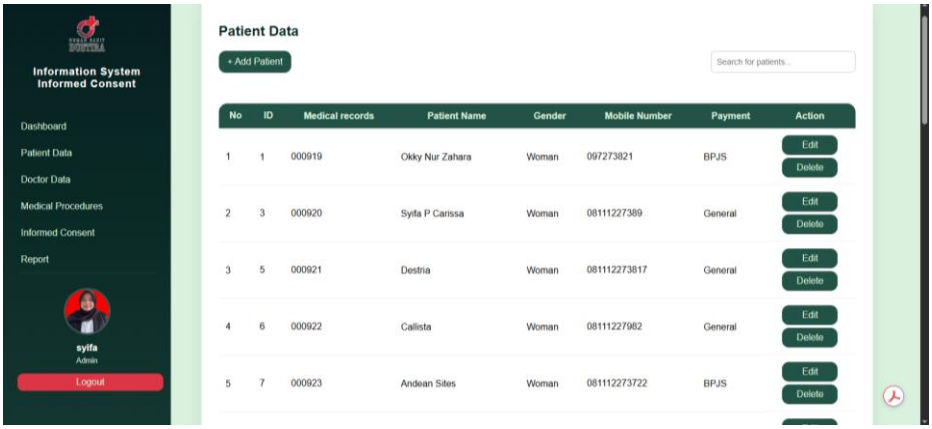


Figure 8. Patient Data Form

Figure 8 presents the patient data form, which is completed and managed by the medical records officer. This form is used to record, update, and maintain patient

identification and demographic information required for the informed consent process. Accurate patient data ensure that informed consent documents are linked to the correct medical record.

Physician Data Page

Figure 9 displays the physician data form containing physician identification and professional information. This form is used to store, update, and manage physician records and to display the list of physicians providing healthcare services. The stored physician data are subsequently used as references when documenting medical procedures and completing informed consent forms.

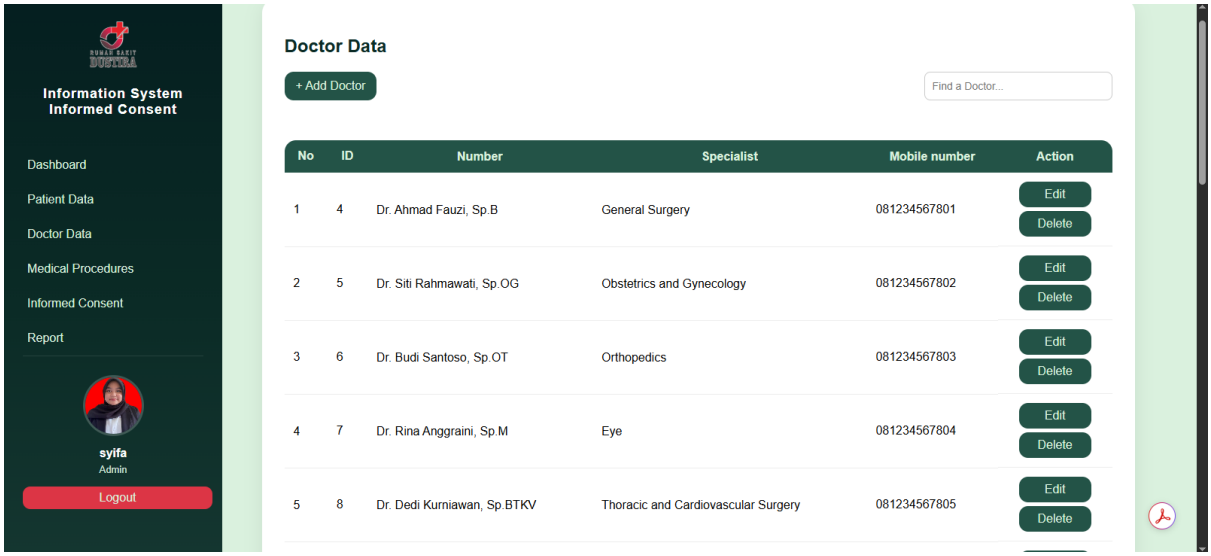


Figure 9. Physician Data Form

Medical Procedure Data Page

Figure 10 presents the medical procedure data form, which is completed by the physician. This form is used to record information regarding the proposed medical procedure for the patient, including the type of procedure, relevant clinical information, potential risks, benefits, alternatives, and other information required before consent is obtained.

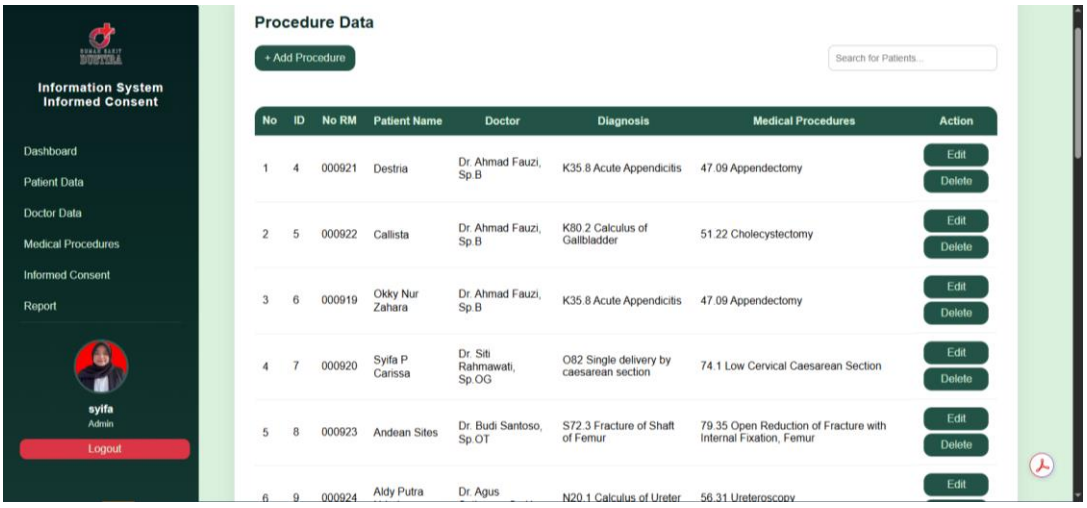


Figure 10. Medical Procedure Data Form

Informed Consent Page

Figure 11 presents the informed consent form generated by the system. This form is used to provide information regarding the proposed medical procedure, record the identity of the person receiving the information, and document the patient's decision to approve or refuse the procedure. The form also includes electronic signature fields for the patient or witness and the physician responsible for the patient's care.

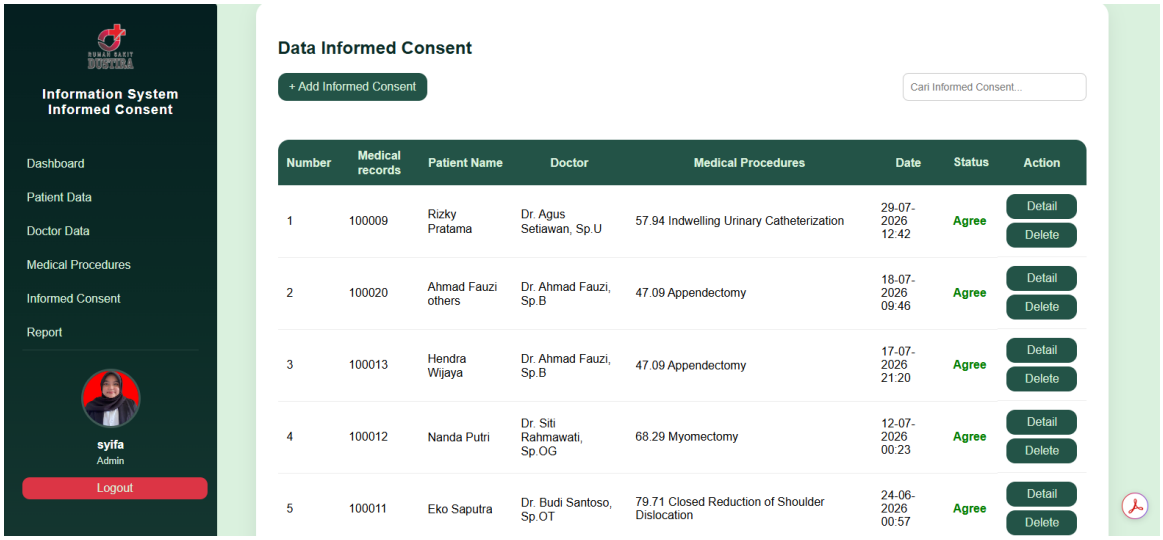


Figure 11. Informed Consent Form

Before entering or confirming informed consent data, authorized personnel are required to enter an access code as an additional security measure. This mechanism helps ensure that only authorized users can access, modify, and validate sensitive informed consent information.

Report Page

Figure 12 illustrates the report page used to display informed consent document records. Medical records officers can filter reports based on the patient's name, a specified period, and the patient's decision regarding the proposed medical procedure. The system also allows informed consent documents to be printed either from the generated report or individually through the manual printing function. This feature supports efficient document retrieval, monitoring, and administrative reporting.

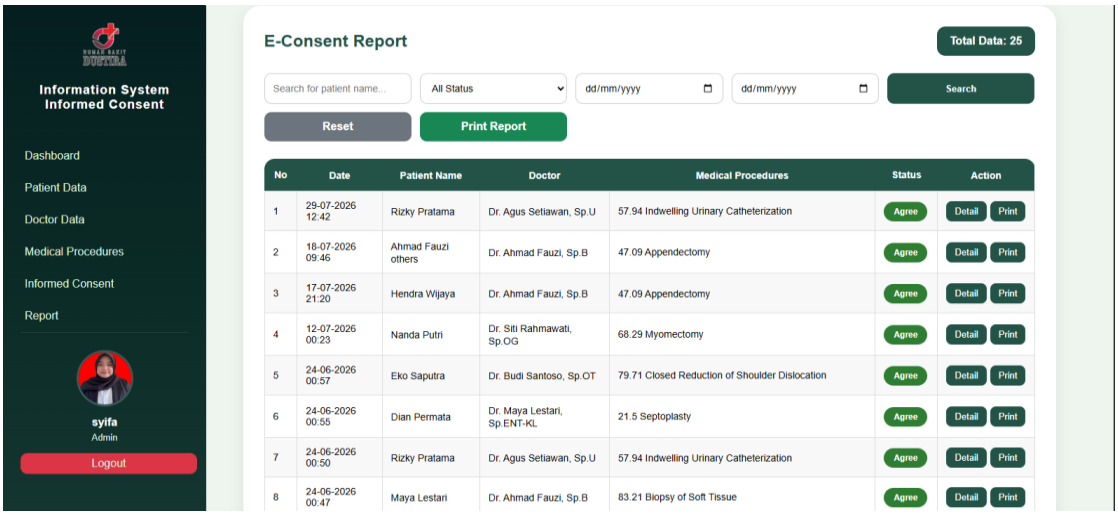
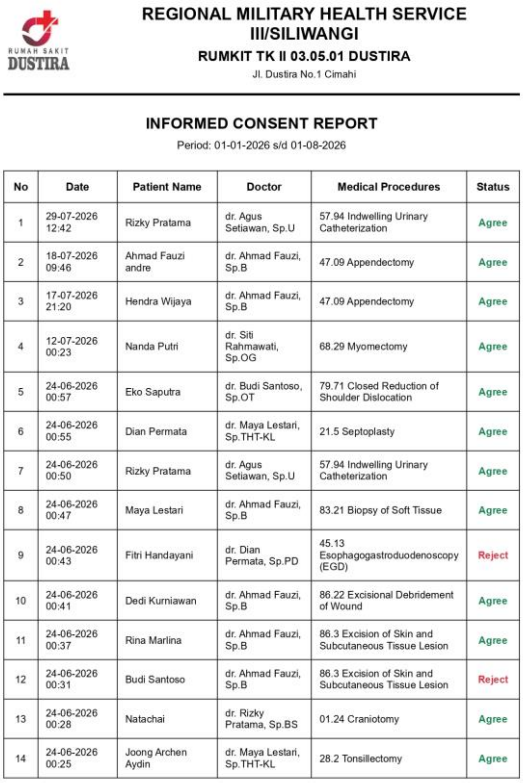


Figure 12. Report Form Based on Patient Name, Period, and Consent Decision

Figure 13 presents the informed consent report filtered by the selected time period, displaying documents based on their creation dates. This feature enables medical records officers to retrieve informed consent records efficiently within a specified reporting period for monitoring, administrative, and documentation purposes.



REGIONAL MILITARY HEALTH SERVICE
III/SILIWANGI
RUMKIT TK II 03.05.01 DUSTIRA
Jl. Dustira No.1 Cimahi

INFORMED CONSENT REPORT
Period: 01-01-2026 s/d 01-08-2026

No	Date	Patient Name	Doctor	Medical Procedures	Status
1	29-07-2026 12:42	Rizky Pratama	dr. Agus Setiawan, Sp.U	57.94 Indwelling Urinary Catheterization	Agree
2	18-07-2026 09:46	Ahmad Fauzi andre	dr. Ahmad Fauzi, Sp.B	47.09 Appendectomy	Agree
3	17-07-2026 21:20	Hendra Wijaya	dr. Ahmad Fauzi, Sp.B	47.09 Appendectomy	Agree
4	12-07-2026 00:23	Nanda Putri	dr. Siti Rahmawati, Sp.OG	68.29 Myomectomy	Agree
5	24-06-2026 00:57	Eko Saputra	dr. Budi Santoso, Sp.OT	79.71 Closed Reduction of Shoulder Dislocation	Agree
6	24-06-2026 00:55	Dian Permata	dr. Maya Lestari, Sp.THT-KL	21.5 Septoplasty	Agree
7	24-06-2026 00:50	Rizky Pratama	dr. Agus Setiawan, Sp.U	57.94 Indwelling Urinary Catheterization	Agree
8	24-06-2026 00:47	Maya Lestari	dr. Ahmad Fauzi, Sp.B	83.21 Biopsy of Soft Tissue	Agree
9	24-06-2026 00:43	Fitri Handayani	dr. Dian Permata, Sp.PD	45.13 Esophagogastroduodenoscopy (EGD)	Reject
10	24-06-2026 00:41	Dedi Kurniawan	dr. Ahmad Fauzi, Sp.B	86.22 Excisional Debridement of Wound	Agree
11	24-06-2026 00:37	Rina Marlina	dr. Ahmad Fauzi, Sp.B	86.3 Excision of Skin and Subcutaneous Tissue Lesion	Agree
12	24-06-2026 00:31	Budi Santoso	dr. Ahmad Fauzi, Sp.B	86.3 Excision of Skin and Subcutaneous Tissue Lesion	Reject
13	24-06-2026 00:28	Natachai	dr. Rizky Pratama, Sp.BS	01.24 Craniotomy	Agree
14	24-06-2026 00:25	Joong Archen Aydin	dr. Maya Lestari, Sp.THT-KL	28.2 Tonsillectomy	Agree

Figure 13. Informed Consent Report Based on Period

Printed Informed Consent Document

Figure 15 illustrates the printed version of the informed consent document generated automatically by the system. The document contains comprehensive information regarding

the proposed medical procedure, patient identification, physician identification, and the patient's consent status, together with authenticated electronic signatures from the patient (or witness) and the responsible physician. Once generated, the document is securely stored within the system as a digital archive, ensuring legal documentation, facilitating efficient record management, and enabling rapid retrieval of informed consent records whenever required. The implementation of digital archiving also minimizes the risk of document loss or physical deterioration while improving the efficiency and reliability of medical records management in healthcare facilities.

REGIONAL MLITARY HEALTH SERVICE III/SILIWANGI
RUMKIT TK II 03.05.01 DUSTIRA
Jl. Dustira No.1 Cimahi

MEDICAL INFORMATION AND INFORMED CONSENT

Patient Name : Eko Saputra
Medical Record : 100011
Physician : dr. Budi Santoso, Sp.OT
Tanggal : 24-06-2026 00:57

MEDICAL INFORMATION

No	Information Type	Information Detail
1	Medical Diagnosis	S43.0 Dislocation of Shoulder Joint
2	Basic of Diagnosis	Physical examination and radiographic (X-ray) evaluation
3	Medical Procedure	79.71 Closed Reduction of Shoulder Dislocation
4	Indication for Procedure	Shoulder joint displacement without major fracture
5	Procedure Methode	Restoration of the shoulder joint position without surgical interventon
6	Purpose	To restore normal shoulder joint function and alignment
7	Prognosis	Favorable with appropriate relabitation
8	Risks	Pain and soft tissue injury
9	Complications	Recurent shoulder disiocation
10	Alternative Treatment	Open reduction Surgery
11	Addtional Risks	Nerve injury

I hereby acknowledge that I have received a complete explanation regarding the propoed medical procedure and fully understand the information provided by the attending physician

INFORMED CONSENT

I, the undersigned, hereby declare that:

Name : Lilis Suryani
Relationship to Patient : Wife
Decision : Agree

I understand the benefits, objective, potential risks, and possible complications of the proposed medical procedure and hereby voluntarily CONSENT to the medical treatment

Patient / Patient's Legal Representative
(Lilis Suryani)

Physician
(dr. Budi Santoso, Sp.OT)

Figure 15. Printed Informed Consent Document

System Testing

The developed web-based Informed Consent Information System was evaluated using the Black-Box Testing method to verify that each functional component operated according to the specified system requirements. This testing approach focuses on validating system functionality without examining the internal program code. The evaluation covered the main system features, including user authentication, patient data management, physician data management, medical procedure management, informed consent processing, report generation, and document printing. The testing results indicate that all functional modules performed successfully and produced outputs consistent with the expected results, demonstrating that the system is reliable and ready to support the electronic management of informed consent in healthcare facilities.

Table 1. Black-Box Testing Results of the Web-Based Informed Consent Information System

No.	Test Scenario	Expected Result	Test Result	Conclusion
1	Enter a valid username and password, then click the **Login** button.	The system successfully redirects the user to the dashboard page.	The user is successfully redirected to the dashboard page.	**Success**
2	Perform Create, Read, Update, and Delete (CRUD) operations on patient data.	The system successfully performs CRUD operations on patient data.	CRUD operations on patient data are successfully completed.	**Success**
3	Perform Create, Read, Update, and Delete (CRUD) operations on physician data.	The system successfully performs CRUD operations on physician data.	CRUD operations on physician data are successfully completed.	**Success**
4	Perform Create, Read, Update, and Delete (CRUD) operations on medical procedure data.	The system successfully performs CRUD operations on medical procedure data.	CRUD operations on medical procedure data are successfully completed.	**Success**
5	Add, display, and delete informed consent records.	The system successfully adds, displays, and deletes informed consent records.	Informed consent records are successfully added, displayed, and deleted.	**Success**
6	Generate informed consent reports.	The system successfully generates informed consent reports based on the selected period and consent decision.	Informed consent reports are successfully generated based on the selected period and consent decision.	**Success**
7	Print informed consent documents and reports.	The system successfully generates printable PDF versions of informed consent documents and reports.	PDF versions of informed consent documents and reports are successfully generated and printed.	**Success**

CONCLUSIONS AND RECOMMENDATIONS

Conclusion

Based on the findings of this study, a web-based Informed Consent Information System was successfully designed and developed to support the electronic management of medical procedure consent. The proposed system provides comprehensive functionalities, including patient data management, physician data management, medical procedure management, informed consent recording, electronic signature integration, and the generation of informed consent documents and reports. The implementation of the system improves the efficiency of managing informed consent documentation, facilitates the storage and retrieval of patient records, and enhances the administrative and legal validity of healthcare services through the use of electronic documents. Future development should focus on incorporating certified digital signatures, integrating the system with Electronic Medical Record (EMR) platforms to improve interoperability, and strengthening data security mechanisms to ensure compliance with healthcare information security standards. These enhancements are expected to support broader implementation and increase the effectiveness of digital informed consent management across healthcare facilities.

Limitations

This study has several limitations. First, the proposed web-based Informed Consent Information System was designed and evaluated within a single healthcare setting, limiting the generalizability of the findings to other hospitals or healthcare institutions with different workflows and organizational requirements. Second, the system evaluation focused primarily on functional testing using the Black-Box Testing approach and did not include comprehensive usability, performance, security, or user acceptance evaluations involving a larger number of healthcare professionals and patients. Third, the current system has not yet been integrated with Electronic Medical Record (EMR) or Hospital Information System (HIS) platforms, thereby limiting interoperability and real-time data exchange. In addition, although the system supports electronic signatures, it does not yet implement certified digital signatures that comply with national electronic transaction regulations. Therefore, the findings should be interprete

Recommendations

Future research should evaluate the proposed web-based Informed Consent Information System in multiple healthcare facilities to assess its scalability, usability, and effectiveness across different clinical environments. Further studies are also recommended to integrate the system with Electronic Medical Record (EMR) and Hospital Information System (HIS) platforms to improve interoperability and streamline clinical workflows. In addition, implementing certified digital signatures that comply with national regulations on electronic transactions would strengthen the legal validity of electronic informed consent documents. Future development should also emphasize advanced data security mechanisms, such as encryption, multi-factor authentication, role-based access control, and audit trails, to enhance the confidentiality, integrity, and availability of patient information. Finally, comprehensive evaluations using usability testing, user acceptance models (e.g., Technology Acceptance Model (TAM) or Unified Theory of Acceptance and Use of Technology (UTAUT)), and performance assessments involving healthcare professionals and patients are recommended to further validate the system's effectiveness and support its broader implementation in healthcare services.

Author Contributions

All authors made significant contributions to this study. These contributions included research conceptualization, development of the theoretical framework, data collection, data analysis, interpretation of results, manuscript preparation, scholarly revision, and final approval of the manuscript for publication. All authors confirm that they have read and approved the final version of the article.

REFERENCES

Aisah, N., & Sari, I. (2024). Analisis desain formulir elektronik general consent rawat jalan di Rumah Sakit X Karawang. Journal of Medical Record Student (JMeRS), 10–15.

Ansori, S., Sari, I., & Sufyana, C. (2022). Sistem Informasi Distribusi Rekam Medis (Studi Kasus: RSAU Lanud Sulaiman). *Jurnal Sains Dan Informatika*, *8*(1), 70-79.

Dewi, G. A. M. P., et al. (2025). Legal and ethical analysis of the implementation of informed consent in medical practice in Indonesia. Babali Nursing Research.

Dewi, S., Asyhadi, F., Amaliya, L., & Gagarin, M. G. (2025). Persetujuan tindakan medik (informed consent) pada pasien anak dan dewasa ditinjau dari perspektif hukum perdata. Al-Zayn: Jurnal Ilmu Sosial & Hukum, 3(4), 4824–4831.

Fajrin, R. N., Yunengsih, Y., & Kusumadiarti, R. S. (2025). Desain sistem informasi kelengkapan formulir Informed Consent rawat inap dengan metode Agile. Jurnal

Informatika dan Komputer (INFOKOM), 13(2), 52–68. https://doi.org/10.56689/infokom.v13i2.2172

Fitriani, F. S., & Ulfah, A. (2024). Analisis digitalisasi formulir Informed Consent pasien ICU dalam menunjang rekam medis elektronik di RSU Hermina Arcamanik. PREPOTIF: Jurnal Kesehatan Masyarakat, 8(2), 3699–3703. https://doi.org/10.31004/prepotif.v8i2.31479

Gesualdo, F., Daverio, M., Palazzani, L., Dimitriou, D., Diez-Domingo, J., Fons-Martinez, J., et al. (2021). Digital tools in the informed consent process: A systematic review. BMC Medical Ethics, 22(1), Article 18. https://doi.org/10.1186/s12910-021-00585-8

Ibrahim, M. M., Rakhmawati, F., Gusti, T. E., Wulandari, A., Maulana, I., & Nadziroh, N. U. (2025). Optimalisasi sistem dokumentasi medis melalui desain antarmuka e-form Informed Consent. JAA (Jurnal ABDIMAS Ar Rahma), 2(2), 60–68.

Jayanto, D. L., Suharlikah, S., & Djusmin, V. (2021). Prototype Informed Consent elektronik UPTD Puskesmas Baron Kabupaten Nganjuk. Jurnal Rekam Medis dan Informasi Kesehatan Indonesia (JURMIKI), 1(1), 1–11.

Kementerian Kesehatan Republik Indonesia. (2022). Peraturan Menteri Kesehatan Republik Indonesia Nomor 24 Tahun 2022 tentang Rekam Medis.

Khairunnisa, C. (2025). Medical ethics implementation of health services in the digital era: A literature review. International Journal of Life Science and Health Research, 3(1), 34–44.

Mundok, M. S., Sufyana, C. M., & Suryani, A. I. (2024). Desain formulir Informed Consent berbasis elektronik guna menunjang efektivitas rekam medis elektronik. Jurnal Teknologi Sistem Informasi dan Aplikasi, 7(3), 1090–1101.

Naurah, G., & Simarmata, M. (2025). The validity of electronic informed consent in hospital services: A juridical analysis based on Law Number 17 of 2023 on Health. Proceedings of the International Conference on Islamic Community Studies, 77–85.

Nurandini, N. I., & Suryani, A. I. (2024). Tinjauan aspek legalitas dan keamanan penggunaan tanda tangan elektronik pada rekam medis elektronik di Rumah Sakit X Kota Cimahi. Media Bina Ilmiah, 19(3), 4015–4022.

Parsons, S. L., Daliya, P., Evans, P., & Lobo, D. N. (2023). Digital informed consent: Modernising information sharing in surgery to empower patients. World Journal of Surgery, 47(3), 649–657. https://doi.org/10.1007/s00268-022-06846-w

Prajany, J. J. (2025). Regulation of ethical aspects of electronic medical records in Indonesia: A normative legal review. Research Horizon, 5(1), 1–12.

Republik Indonesia. (2008). Undang-Undang Republik Indonesia Nomor 11 Tahun 2008 tentang Informasi dan Transaksi Elektronik. Pemerintah Republik Indonesia.

Republik Indonesia. (2022). Undang-Undang Republik Indonesia Nomor 27 Tahun 2022 tentang Perlindungan Data Pribadi. Pemerintah Republik Indonesia.

Republik Indonesia. (2023). Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 tentang Kesehatan. Pemerintah Republik Indonesia.

Schulz, A., & Bohnet-Joschko, S. (2024). Enhancing patient informed consent in elective skin cancer surgeries: A comparative study of traditional and digital approaches in a German public hospital. BMC Health Services Research, 24, 1024. https://doi.org/10.1186/s12913-024-11346-1

Shah, P., Thornton, I., Turrin, D., & Hipskind, J. E. (2024). Informed consent. In StatPearls. StatPearls Publishing.

Winarti, W., & Rizka, R. (2025). Informed Consent sebagai upaya perlindungan hukum bagi tenaga kesehatan dalam kasus medis darurat (Studi kasus di Rumah Sakit Umum Daerah Provinsi Papua Barat). SEHATRAKYAT (Jurnal Kesehatan Masyarakat), 4(2), 264–277. https://doi.org/10.54259/sehatrakyat.v4i2.4310