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Patient Protection in Research-Based Hospital Services

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Keywords:

patient protection; hospital services; clinical research; informed consent; health data; research ethics

ABSTRACT

This study examined patient protection when research is embedded in hospital services. Normative legal research used statutory, conceptual, and comparative approaches based on Indonesian health, clinical-trial, ethics, medical-record, and personal-data rules, international ethical standards, and recent scholarship. The study found fragmented protection at the boundary between individualized care and research, particularly concerning therapeutic misunderstanding, consent quality, secondary data use, injury, compensation, and continuity of care. It proposes a Research-Based Hospital Patient Protection Model comprising activity classification, proportional review, layered consent with comprehension assurance, integrated safety monitoring, transparent data governance, and no-fault-oriented compensation with independent complaints. The model assigns verifiable duties to hospitals, investigators, sponsors, ethics committees, and regulators. It recommends a national technical standard, hospital research ombuds functions, secured injury funding, and integrated safety and data reporting.

Kata Kunci:

perlindungan pasien; pelayanan rumah sakit; penelitian klinis; persetujuan setelah penjelasan; data kesehatan; etika penelitian

ABSTRAK

Penelitian ini menganalisis perlindungan pasien ketika penelitian melekat pada pelayanan rumah sakit. Penelitian hukum normatif menggunakan pendekatan peraturan perundang-undangan, konseptual, dan komparatif berdasarkan pengaturan kesehatan, uji klinis, etika, rekam medis, serta pelindungan data pribadi, standar etik internasional, dan literatur mutakhir. Hasil penelitian menunjukkan fragmentasi perlindungan pada batas antara pelayanan individual dan penelitian, terutama terkait kesalahpahaman terapeutik, mutu persetujuan, penggunaan sekunder data, cedera, kompensasi, dan kesinambungan perawatan. Penelitian ini mengusulkan Model Perlindungan Pasien Rumah Sakit Berbasis Penelitian yang meliputi klasifikasi kegiatan, penelaahan proporsional, persetujuan berlapis dengan verifikasi pemahaman, pemantauan keselamatan terintegrasi, tata kelola data transparan, serta kompensasi berorientasi tanpa kesalahan dan pengaduan independen. Model menetapkan kewajiban terukur bagi rumah sakit, peneliti, sponsor, komite etik, dan regulator, disertai rekomendasi standar teknis nasional, ombuds penelitian, pendanaan cedera, serta pelaporan keselamatan dan data terintegrasi.

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A. Introduction

Hospitals increasingly combine diagnosis and treatment with clinical trials, pragmatic studies, biobanking, algorithm evaluation, and the secondary use of electronic medical records. Indonesia's clinical-research activity grew by 83 percent over fifteen years and reached sixty-six trials in 2024, indicating that more patients may encounter research while receiving ordinary hospital care. This development can accelerate access to knowledge and innovation, but it also changes the legal position of the patient. A person who enters a hospital seeking treatment may simultaneously become a prospective participant, a source of identifiable health data, or a contributor of biological material. The protection problem arises when the transition from patient to participant is not clearly disclosed, when clinical dependence influences consent, or when institutional responsibilities are divided among the hospital, investigator, sponsor, research ethics committee, and regulator. Patient protection must therefore operate before recruitment, throughout the intervention, during data processing, and after research-related harm or withdrawal.[1]

Indonesia's current legal architecture provides several protection layers. Law Number 17 of 2023 on Health regulates health rights, health-service facilities, information, medical action, research, supervision, and responsibility. Government Regulation Number 28 of 2024 implements that statute and consolidates rules that previously appeared in separate health-sector regulations. Clinical trials also require approval and control under the Regulation of the Food and Drug Authority Number 8 of 2024, as amended by Regulation Number 34 of 2025. These instruments coexist with ethics-review rules, medical-record governance, and the Personal Data Protection Law. Their coexistence does not automatically create an integrated protection system. Each instrument addresses a different object, decision-maker, or procedural stage. A hospital may comply with clinical-service requirements while failing to explain a research component, or obtain ethics approval while leaving

[1] World Health Organization Indonesia, "Driving Clinical Trials in Indonesia through Collaborative Action," January 6, 2026, https://www.who.int/indonesia/news/detail/06-01-2026-driving-clinical-trials-in-indonesia-through-collaborative-action.

unclear who must finance emergency treatment and compensation when a participant is injured.[234]

Meaningful informed consent remains the first point of vulnerability. Empirical research shows that signing a form does not consistently demonstrate that participants understand randomization, alternatives, foreseeable risks, voluntariness, or the distinction between research and individualized treatment. Therapeutic misunderstanding becomes particularly acute when the treating physician is also the investigator and when patients interpret an invitation as a professional recommendation designed primarily for their own clinical benefit. Long technical documents, unequal health literacy, time pressure, severe illness, and family dependence may further reduce comprehension. A hospital-based consent process must consequently be assessed through the quality of communication and the freedom of decision, not through the existence of a signature alone. The law should treat comprehension verification, opportunity for questions, accessible language, and protection against retaliation for refusal as operational duties that can be audited.[567]

The expansion of learning health systems creates a second protection problem. Routine clinical data can be reused to compare treatments, improve workflows, train predictive systems, or generate publishable evidence. Such reuse may impose minimal physical risk, yet it can expose patients to privacy breaches,

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[2] Republic of Indonesia, *Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan*, Lembaran Negara Republik Indonesia Tahun 2023 Nomor 105, Tambahan Lembaran Negara Republik Indonesia Nomor 6887.

[3] Republic of Indonesia, *Peraturan Pemerintah Nomor 28 Tahun 2024 tentang Peraturan Pelaksanaan Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan*, Lembaran Negara Republik Indonesia Tahun 2024 Nomor 135, Tambahan Lembaran Negara Republik Indonesia Nomor 6952.

[4] Badan Pengawas Obat dan Makanan Republik Indonesia, *Peraturan Badan Pengawas Obat dan Makanan Nomor 8 Tahun 2024 tentang Tata Laksana Persetujuan Pelaksanaan Uji Klinik*, as amended by *Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2025*.

[5] Chengai Wu et al., "Participants' Understanding of Informed Consent in Clinical Trials: A Systematic Review and Updated Meta-Analysis," *PLOS ONE* 19, no. 1 (2024): e0295784, https://doi.org/10.1371/journal.pone.0295784.

[6] Sarah Heynemann et al., "Therapeutic Misunderstandings in Modern Research," *Bioethics* 38, no. 2 (2024): 138–152, https://doi.org/10.1111/bioe.13241.

[7] Tomasz Pietrzykowski and Katarzyna Smilowska, "The Reality of Informed Consent: Empirical Studies on Patient Comprehension: Systematic Review," *Trials* 22 (2021): 57, https://doi.org/10.1186/s13063-020-04969-w.

re-identification, discriminatory profiling, unauthorized commercial use, and decisions based on inaccurate data. Electronic records also make the distinction between direct care, quality improvement, and research less visible to patients. Indonesian personal-data and medical-record rules provide a basis for confidentiality, security, access control, and lawful processing, but hospitals still need a defensible method for classifying secondary uses and informing patients. Broad consent, opt-out systems, waivers, and project-specific consent produce different effects on participation, representativeness, and autonomy. The appropriate model should be proportionate to risk while retaining transparency and meaningful choice.[89]

Research-related injury and economic burden expose a third gap. Participation may generate adverse reactions, additional examinations, transport costs, lost income, or delayed access to standard treatment. Payment for time and inconvenience must be distinguished from compensation for injury and from impermissible inducement. Participants should not have to prove professional negligence before receiving necessary treatment for harm causally connected to a protocol, because many injuries occur despite technically correct conduct. At the same time, causation standards, exclusions, insurance coverage, and the relationship between sponsor and hospital liability must be stated before recruitment. Without an institutional mechanism, a participant may be referred among the investigator, sponsor, insurer, and hospital while urgent care is delayed. Effective protection requires a pre-funded route for immediate clinical care, impartial causation assessment, compensation, and review of disputed decisions.[1011]

[8] Jan Piasecki et al., "Ethical Issues in Biomedical Research Using Electronic Health Records: A Systematic Review," *Medicine, Health Care and Philosophy* 24, no. 4 (2021): 633–658, https://doi.org/10.1007/s11019-021-10031-6.

[9] Republic of Indonesia, *Undang-Undang Nomor 27 Tahun 2022 tentang Pelindungan Data Pribadi*, Lembaran Negara Republik Indonesia Tahun 2022 Nomor 196, Tambahan Lembaran Negara Republik Indonesia Nomor 6820; Republic of Indonesia, Ministry of Health, *Peraturan Menteri Kesehatan Nomor 24 Tahun 2022 tentang Rekam Medis*, Berita Negara Republik Indonesia Tahun 2022 Nomor 829.

[10] Joanna Różyńska, "The Ethical Anatomy of Payment for Research Participants," *Medicine, Health Care and Philosophy* 25 (2022): 449–464, https://doi.org/10.1007/s11019-022-10092-1.

[11] Matt Lamkin, "Avoiding Exploitation in Phase I Clinical Trials: More Than (Un)Just Compensation," *Journal of Law and the Biosciences* 5, no. 1 (2018): 169–206.

Previous scholarship has examined informed consent in learning health systems, ethical issues in electronic-record research, public preferences regarding transparency, and consent bias in secondary data use. Other studies have analyzed therapeutic misunderstanding, participant comprehension, payment, and exploitation. These studies establish important safeguards, but they generally focus on a single ethical problem or on health systems outside Indonesia. Indonesian regulations likewise specify separate requirements for health services, ethics review, clinical-trial approval, data protection, and medical records. A remaining research gap concerns how those protections should be connected at hospital level when care and research occur in the same encounter. The central issue is institutional design: who classifies the activity, who verifies consent quality, who monitors safety, who controls data access, who pays for injury, and where a patient can complain without affecting treatment. This article addresses that gap through an integrated, hospital-centered model.[12][13]

This study examines two questions. First, how should Indonesian law distinguish and integrate patient-care and research-participant protections when research is embedded in hospital services? Second, what institutional model can secure meaningful consent, privacy, safety, compensation, and accountability across the research lifecycle? The article's novelty lies in the Research-Based Hospital Patient Protection Model. The model connects six protection gates: activity classification, proportionate ethical and scientific review, layered consent with comprehension assurance, safety monitoring and continuity of care, controlled and transparent data use, and no-fault-oriented compensation with independent complaints. It does not treat ethics approval as a substitute for hospital responsibility. Instead, it allocates duties among the board of directors, clinical unit, investigator, sponsor, data-protection function, ethics committee, and regulator. This structure converts abstract rights into verifiable institutional controls and

[12] Annabelle Cumyn et al., "Informed Consent within a Learning Health System: A Scoping Review," *Learning Health Systems* 4, no. 2 (2020): e10206, https://doi.org/10.1002/lrh2.10206.

[13] Annabelle Cumyn et al., "Patients' and Members of the Public's Wishes Regarding Transparency in the Context of Secondary Use of Health Data: Scoping Review," *Journal of Medical Internet Research* 25 (2023): e45002, https://doi.org/10.2196/45002.

preserves protection when a patient refuses participation or withdraws after enrollment.

B. Research Method

This study used normative legal research with statutory, conceptual, and comparative approaches. The statutory materials included Law Number 17 of 2023 on Health, Government Regulation Number 28 of 2024, the Personal Data Protection Law, regulations on medical records, national health-research ethics committees, and clinical-trial approval. International ethical and technical benchmarks included the 2024 Declaration of Helsinki, ICH E6(R3) Good Clinical Practice, and the 2024 World Health Organization guidance on best practices for clinical trials. The conceptual analysis examined patient autonomy, therapeutic misunderstanding, proportionality, research-related injury, institutional accountability, and data stewardship. Comparative insights were drawn from recent peer-reviewed studies on learning health systems, embedded research, informed consent, secondary data use, and participant payment. Materials published principally between 2018 and 2026 were collected through document review. The analysis identified the legal function of each protection, mapped overlaps and gaps across the research lifecycle, and constructed a prescriptive model by linking risks, responsible actors, institutional controls, and patient-facing remedies.

C. Discussion

1. Legal and Ethical Gaps in Research-Based Hospital Services

a. The Blurred Boundary between Treatment and Research

Clinical care and research pursue overlapping but legally distinct objectives. Clinical decisions are ordinarily justified by the expected interests of an individual patient, whereas research follows a protocol designed to produce generalizable knowledge. A research intervention may offer potential benefit, but its allocation, timing, dosage, or data collection is determined partly by scientific requirements. The distinction matters because a patient may reasonably assume that every test or treatment proposed in a hospital has been selected exclusively for personal benefit. Embedded and pragmatic trials intentionally use routine workflows, which

improves relevance but can make the research layer difficult to identify. The hospital must therefore disclose when a clinical choice is constrained by randomization, protocol eligibility, additional sampling, or research endpoints. Classification should depend on purpose, method, and deviation from individualized care rather than on the label used by an investigator.[14]

Therapeutic misunderstanding is not limited to a participant's lack of technical knowledge. It can arise from the institutional authority of hospitals and physicians. Patients may believe that refusal will reduce attention, damage the physician relationship, or eliminate access to needed treatment. This pressure is stronger where specialist services are scarce or where research offers an intervention that is otherwise unaffordable. The treating physician may ethically introduce a study, but consent should be obtained or verified by a person who can distinguish clinical recommendation from recruitment. The discussion must state which procedures are standard care, which are research-only, what alternatives remain available, and what will happen after refusal. A research invitation should never be integrated into admission documents in a manner that makes consent appear mandatory for treatment.[15][16]

The care-research boundary is also blurred by quality-improvement activities. Hospitals routinely audit infection rates, medication errors, length of stay, and treatment outcomes. Some projects remain internal operational evaluation, while others use systematic interventions, comparison groups, randomization, or publication plans that resemble research. Publication intent alone is not decisive, but the combination of generalizable aims and prospective alteration of patient care should trigger ethics review. A dual-use category is needed for activities that serve immediate quality goals while producing research outputs. This category prevents strategic relabeling and allows proportionate review. It should also ensure that

[14] Annabelle Cumyn et al., "Informed Consent within a Learning Health System: A Scoping Review," *Learning Health Systems* 4, no. 2 (2020): e10206, https://doi.org/10.1002/lrh2.10206.

[15] Sarah Heynemann et al., "Therapeutic Misunderstandings in Modern Research," *Bioethics* 38, no. 2 (2024): 138–152, https://doi.org/10.1111/bioe.13241.

[16] Paula Aristizabal et al., "Assessment of Factors Associated with Parental Perceptions of Voluntary Decisions about Child Participation in Leukemia Clinical Trials," *JAMA Network Open* 4, no. 5 (2021): e219038, https://doi.org/10.1001/jamanetworkopen.2021.9038.

patients receive information when an improvement project changes treatment allocation, increases data exposure, or introduces risks beyond ordinary care.[17]

Special protection is required when decision-making capacity is impaired, when treatment is urgent, or when children are involved. Substitute permission cannot eliminate the duty to seek assent and respect dissent according to the person's capacity. Emergency research may justify modified consent only under narrowly defined conditions, independent review, community engagement where appropriate, and prompt information when the patient or representative becomes available. For pediatric and dependent patients, recruitment by the treating team requires additional scrutiny because access to care and parental anxiety can affect voluntariness. The hospital should document why inclusion is scientifically necessary, why the risk is proportionate, and what independent support was offered. Vulnerability should lead to tailored safeguards rather than automatic exclusion that deprives groups of evidence relevant to their care.[18]

b. Fragmented Protection under Health, Research, and Data Law

The Health Law and its implementing regulation provide the broad foundation for patient rights and institutional responsibility, but hospital-based research activates several additional regimes. Ethics committees assess scientific validity, risk-benefit proportionality, consent, privacy, and participant selection. The Food and Drug Authority controls regulated clinical trials and requires compliance with good clinical practice. Medical-record rules govern the creation, storage, access, and confidentiality of clinical documentation. Personal-data law governs processing purposes, security, data-subject rights, and accountability. These regimes should be read cumulatively. Approval from one body does not waive duties arising under another. A favorable ethics opinion does not authorize insecure data processing, and regulatory approval does not release the hospital from

[17] Emma Friedman et al., "Implications for Precision Accelerated Clinically Embedded Research: A Novel Technology-Enabled Approach to Conducting Minimal-Risk Research in Outpatient Community Healthcare Settings," *PLOS ONE* 20, no. 4 (2025): e0318533, https://doi.org/10.1371/journal.pone.0318533.

[18] World Medical Association, "WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants," adopted October 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki/.

ensuring competent staff, emergency capacity, truthful communication, and continuity of treatment.[19][20][21]

Institutional fragmentation produces practical ambiguity. A sponsor designs the protocol and finances the study, an investigator recruits and treats participants, a hospital provides facilities and emergency support, a contract research organization may monitor compliance, an ethics committee reviews the protocol, and a regulator authorizes specified trials. Contracts often allocate financial risk among these actors, but patients are not parties to those agreements. Protection cannot depend on internal indemnity clauses that are inaccessible to participants. The hospital remains the visible care institution and should establish a single patient-facing responsibility channel. It may later recover costs from a sponsor or insurer, but it should not postpone treatment or complaint handling while contractual responsibility is disputed. The board of directors must know which studies operate within the facility and confirm that resources, insurance, data systems, and personnel match the approved protocol.[22][23]

Research documentation also intersects with the clinical record. Information necessary for safe treatment, including investigational products, adverse reactions, protocol restrictions, and emergency unblinding procedures, should be available to authorized clinicians. Research data that are not necessary for direct care should be separated or access-restricted to avoid unnecessary disclosure. This dual-record approach requires interoperability without unlimited visibility. Access logs, role-based authorization, encryption, retention schedules, and incident response should apply across hospital and sponsor systems. When data leave the hospital, the

[19] Republic of Indonesia, *Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan*, Lembaran Negara Republik Indonesia Tahun 2023 Nomor 105, Tambahan Lembaran Negara Republik Indonesia Nomor 6887.

[20] Republic of Indonesia, Ministry of Health, *Peraturan Menteri Kesehatan Nomor 75 Tahun 2020 tentang Komite Etik Penelitian dan Pengembangan Kesehatan Nasional*, Berita Negara Republik Indonesia Tahun 2020 Nomor 1289.

[21] Badan Pengawas Obat dan Makanan Republik Indonesia, *Peraturan Badan Pengawas Obat dan Makanan Nomor 8 Tahun 2024 tentang Tata Laksana Persetujuan Pelaksanaan Uji Klinik*, as amended by *Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2025*.

[22] International Council for Harmonisation, *ICH E6(R3) Guideline for Good Clinical Practice* (Geneva: ICH, 2025).

[23] World Health Organization, *Guidance for Best Practices for Clinical Trials* (Geneva: World Health Organization, 2024), https://www.who.int/publications/i/item/9789240097711.

agreement must specify purpose limitation, security standards, onward transfer, breach notification, return or destruction, and responsibility for data-subject requests. De-identification reduces risk but should not be treated as irreversible where linkage keys or rich datasets permit re-identification.[2425]

A further gap concerns oversight after initial approval. Ethics review can become document-centered if committees lack timely safety information, protocol-deviation data, or access to participants' complaints. Annual reports are insufficient for high-risk interventions or rapidly changing evidence. Hospitals need continuing review linked to pharmacy, laboratory, incident-reporting, mortality-review, and patient-safety systems. Serious adverse events should trigger parallel clinical response and research assessment. The clinical question is what care the patient requires immediately. The research question is whether the event is expected, related, and capable of changing the risk-benefit balance. Separating these questions prevents uncertainty about attribution from delaying treatment. It also permits suspension of enrollment or modification of the protocol before formal regulatory action is completed.[26]

c. Consent, Vulnerability, Data Reuse, and Research-Related Injury

Consent should be understood as a continuing communicative process. A valid form must be preceded by concise disclosure of purpose, procedures, randomization, alternatives, foreseeable burdens, potential benefits, confidentiality, compensation, contacts, and the right to refuse or withdraw. Information should be layered. A short core document can state decisions that materially affect participation, while annexes explain scientific details, data flows, insurance, and optional future use. This format addresses the failure of long forms that technically disclose everything but obscure the facts most relevant to choice. Hospitals should use plain language, translated or accessible formats, adequate deliberation time, and

[24] Republic of Indonesia, Ministry of Health, *Peraturan Menteri Kesehatan Nomor 24 Tahun 2022 tentang Rekam Medis*, Berita Negara Republik Indonesia Tahun 2022 Nomor 829.

[25] Jan Piasecki et al., "Ethical Issues in Biomedical Research Using Electronic Health Records: A Systematic Review," *Medicine, Health Care and Philosophy* 24, no. 4 (2021): 633–658, https://doi.org/10.1007/s11019-021-10031-6.

[26] International Council for Harmonisation, *ICH E6(R3) Guideline for Good Clinical Practice* (Geneva: ICH, 2025).

trained interpreters. Consent should be renewed when material risks, procedures, data uses, or post-trial arrangements change.[27][28]

Comprehension assurance must be proportionate to risk. For minimal-risk record studies, a brief confirmation may be sufficient. For invasive or high-risk trials, the consent process should include teach-back questions that require the participant to explain the study in their own words. Incorrect answers should lead to renewed explanation, not automatic exclusion. The record should document topics discussed, questions raised, persons present, and any decision-making support. Digital consent may improve access and auditability, but it must not become a sequence of unread screens. Systems should allow patients to pause, download information, contact a human adviser, and change optional choices without losing clinical services. Comprehension data can be audited to identify investigators or study sites that repeatedly obtain formal consent without adequate understanding.[29][30]

Secondary use of routine data requires a differentiated approach. Project-specific consent maximizes control but may be impracticable for large retrospective datasets and can create selection bias. Broad consent can cover defined categories of future research if governance, limits, and withdrawal mechanisms are clear. An opt-out model may be defensible for low-risk public-interest research when recontact is impracticable, data are protected, ethics review approves the waiver, and transparency is genuine. Hospitals should avoid treating silence as unlimited authorization. Patients should be able to view major categories of data use, exclude sensitive uses where feasible, and understand whether commercial partners receive

[27] Chengai Wu et al., "Participants' Understanding of Informed Consent in Clinical Trials: A Systematic Review and Updated Meta-Analysis," *PLOS ONE* 19, no. 1 (2024): e0295784, https://doi.org/10.1371/journal.pone.0295784.

[28] World Medical Association, "WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants," adopted October 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki/.

[29] Tomasz Pietrzykowski and Katarzyna Smilowska, "The Reality of Informed Consent: Empirical Studies on Patient Comprehension: Systematic Review," *Trials* 22 (2021): 57, https://doi.org/10.1186/s13063-020-04969-w.

[30] Paula Aristizabal et al., "Assessment of Factors Associated with Parental Perceptions of Voluntary Decisions about Child Participation in Leukemia Clinical Trials," *JAMA Network Open* 4, no. 5 (2021): e219038, https://doi.org/10.1001/jamanetworkopen.2021.9038.

access. A meta-consent or preference-management system can record choices across research types and revisit them when risk or purpose changes.[31]

Vulnerability and injury protection must also be integrated into consent. Payment should reimburse reasonable expenses and recognize time or inconvenience without being structured to neutralize attention to serious risks. The amount, payment schedule, and consequences of withdrawal should be disclosed. Participants should retain payment already earned and should not be penalized for stopping. Consent documents must identify who will provide and finance treatment for research-related injury, how causation will be assessed, what losses may be compensated, and how a denial can be reviewed. A clause requiring waiver of legal rights is incompatible with meaningful protection. The hospital should explain these arrangements orally because participants may otherwise interpret the mere mention of insurance as a guarantee of broad coverage.[32]

2. An Integrated Patient Protection Model for Research-Based Hospital Services

a. Classification and Proportional Review

The proposed model begins with mandatory classification before any patient is approached or data are accessed. A hospital Research-Care Classification Panel should categorize each activity as ordinary clinical care, quality improvement, human-participant research, or dual-use activity. The panel should include clinical governance, research administration, ethics, patient safety, legal, and data-protection expertise. Classification should examine the primary purpose, prospective alteration of care, randomization, additional procedures, identifiability of data, external transfer, commercial involvement, and intention to generate generalizable knowledge. The decision and reasons should be recorded.

[31] Yvonne de Man et al., "Opt-In and Opt-Out Consent Procedures for the Reuse of Routinely Recorded Health Data in Scientific Research and Their Consequences for Consent Rate and Consent Bias: Systematic Review," *Journal of Medical Internet Research* 25 (2023): e42131, https://doi.org/10.2196/42131.

[32] Joanna Różyńska, "The Ethical Anatomy of Payment for Research Participants," *Medicine, Health Care and Philosophy* 25 (2022): 449–464, https://doi.org/10.1007/s11019-022-10092-1.

Investigators may appeal to the ethics committee, but they should not self-classify a project whose approval determines their ability to proceed.[33]

Classification must lead to proportional review rather than a binary choice between full review and no oversight. Minimal-risk secondary data projects may receive expedited review if data minimization, security, and public-interest criteria are met. Studies that alter treatment, involve vulnerable groups, use invasive procedures, or create substantial informational risk require full ethics and scientific review. Dual-use activities should receive targeted review of the elements that exceed routine quality governance. The hospital should maintain a public registry containing the study title, responsible unit, status, general purpose, and contact channel, subject to justified confidentiality. Community consultation is particularly valuable for nonconsent pragmatic trials because it can reveal acceptability concerns that professional reviewers overlook.[34]

No study should open until the hospital verifies operational readiness. The verification should cover ethics approval, regulatory authorization where required, investigator qualifications, pharmacy and laboratory capacity, emergency procedures, insurance or compensation funding, data-processing agreements, consent materials, recruitment methods, and conflict-of-interest disclosure. Site initiation should be documented by the hospital, not left solely to the sponsor. A change-control procedure must determine whether amendments require new ethics review, regulatory notification, re-consent, staff training, or revised data safeguards. This gate prevents a legally approved protocol from being implemented in a facility that lacks the personnel or systems needed to protect participants.[35]

The proportionality principle should continue throughout the study. Monitoring intensity must reflect intervention risk, population vulnerability, data

[33] International Council for Harmonisation, *ICH E6(R3) Guideline for Good Clinical Practice* (Geneva: ICH, 2025).

[34] Emily A. Largent et al., "The Ethical Value of Consulting Community Members in Nonconsent Pragmatic Clinical Trials," *Clinical Trials* 22 (2025), https://doi.org/10.1177/17407745241259360.

[35] Badan Pengawas Obat dan Makanan Republik Indonesia, *Peraturan Badan Pengawas Obat dan Makanan Nomor 8 Tahun 2024 tentang Tata Laksana Persetujuan Pelaksanaan Uji Klinik*, as amended by *Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2025*.

sensitivity, prior safety signals, and protocol complexity. Low-risk studies can use centralized and risk-based monitoring, while high-risk trials require more frequent site review, independent safety oversight, and rapid escalation. Proportionality does not permit reduced attention to fundamental rights. Every study, including minimal-risk research, requires a lawful purpose, confidentiality, accurate information, voluntary participation where consent applies, and an accessible complaint route. The model therefore reduces unnecessary procedural burden without creating an unregulated category of research.[36]

b. Layered Consent and Comprehension Assurance

The second gate uses a layered consent architecture. The first layer is a concise decision sheet stating that the activity is research, why the patient is invited, how participation differs from ordinary care, principal risks and burdens, available alternatives, and the consequences of refusal. The second layer provides protocol-specific detail, including data use, biological materials, payment, injury arrangements, post-trial access, and contacts. Optional components such as future data use, genomic analysis, commercial collaboration, or recontact should use separate choices. Bundling optional activities into a single mandatory signature undermines voluntariness. The hospital should approve the consent architecture and verify that recruitment materials do not exaggerate benefit or describe research as free treatment.[37][38]

Consent quality should be measured. High-risk studies should use a short teach-back tool covering purpose, randomization where relevant, major risks, alternatives, voluntary participation, and injury procedures. The result should be recorded without turning the interaction into an examination. Repeated misunderstanding should prompt revision of the information materials or retraining of the team. Where the treating clinician has a dependent relationship with the

[36] World Health Organization, *Guidance for Best Practices for Clinical Trials* (Geneva: World Health Organization, 2024), https://www.who.int/publications/i/item/9789240097711.

[37] Annabelle Cumyn et al., "Informed Consent within a Learning Health System: A Scoping Review," *Learning Health Systems* 4, no. 2 (2020): e10206, https://doi.org/10.1002/lrh2.10206.

[38] World Medical Association, "WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants," adopted October 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki/.

patient, an independent consent professional or patient advocate should confirm voluntariness. Family involvement may support decision-making, but the competent patient's own preference remains controlling. For persons with limited capacity, supported decision-making should be attempted before substitute permission is used.[39]

Withdrawal must be operationally real. Participants should be able to withdraw through the investigator, a central hospital contact, or a digital channel. The hospital must explain which activities stop immediately, which safety follow-up remains advisable, and whether data already incorporated into validated analyses can be removed. Withdrawal from research must not terminate clinically indicated treatment or access to the institution. Where new findings materially affect willingness to continue, re-consent is required. At study completion, participants should be offered an understandable summary of general results and, where scientifically valid and appropriately counseled, relevant individual findings. This closes the communication cycle and recognizes participants as rights-holders rather than data sources.[40]

c. Safety Monitoring and Continuity of Care

The third gate integrates research safety with the hospital's clinical safety system. Before enrollment, the protocol should identify anticipated adverse events, stopping rules, emergency treatment, unblinding procedures, referral pathways, and responsible clinicians. During the study, suspected serious adverse events require immediate clinical care and timely notification to the sponsor, ethics committee, hospital leadership, and regulator as applicable. Treatment should not wait for a final determination that the event was caused by the study. The hospital should create a single incident record linked to both the clinical chart and the research file,

[39] Chengai Wu et al., "Participants' Understanding of Informed Consent in Clinical Trials: A Systematic Review and Updated Meta-Analysis," *PLOS ONE* 19, no. 1 (2024): e0295784, https://doi.org/10.1371/journal.pone.0295784.

[40] World Medical Association, "WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants," adopted October 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki/.

with access controls appropriate to each purpose. This prevents duplicate or inconsistent reporting and allows patterns across studies to be detected.[41]

Independent safety oversight is necessary when investigators or sponsors have financial, academic, or reputational interests in continuation. A data and safety monitoring board should be used for trials with substantial risk, vulnerable populations, mortality endpoints, or complex adaptive designs. The board must receive sufficiently current and unblinded information to recommend continuation, modification, suspension, or termination. Hospital leadership should retain authority to stop local enrollment when patient safety is threatened, even before a sponsor reaches a system-wide decision. Conflict-of-interest management should include disclosure, role separation, independent outcome assessment where feasible, and limits on recruitment by clinicians whose patients may feel unable to refuse.[42]

Continuity of care is part of research protection. Participants who experience harm, withdraw, or complete the protocol may require follow-up beyond the formal study visit schedule. The handover plan should identify responsible clinicians, access to investigational or standard alternatives, communication with primary treating teams, and preservation of relevant records. If an investigational intervention has produced benefit, post-trial access should be considered according to evidence, feasibility, and prior commitments. The hospital should not allow the end of sponsor funding to create an abrupt clinical gap. Costs and responsibilities for continuing care should be agreed before recruitment and described in the protocol, consent materials, and hospital-sponsor contract.[43]

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[41] Badan Pengawas Obat dan Makanan Republik Indonesia, *Peraturan Badan Pengawas Obat dan Makanan Nomor 8 Tahun 2024 tentang Tata Laksana Persetujuan Pelaksanaan Uji Klinik*, as amended by *Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2025*.

[42] International Council for Harmonisation, *ICH E6(R3) Guideline for Good Clinical Practice* (Geneva: ICH, 2025).

[43] World Medical Association, "WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants," adopted October 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki/.

d. Data Governance, Transparency, and Secondary Use

The fourth gate treats health data as a protected clinical resource and a research asset subject to stewardship. Every project should have a data map identifying sources, variables, identifiers, legal basis, access roles, recipients, storage location, retention, and deletion or archival rules. Data minimization should be applied at extraction, not after a complete record has been copied. Pseudonymization keys should be held separately and access should be logged. High-risk processing, including genomic information, linkage across institutions, artificial-intelligence development, or cross-border transfer, should undergo a data-protection impact assessment. Security duties must extend to sponsors, vendors, cloud providers, and research partners through enforceable contracts and audit rights.[44]

Transparency should not depend solely on a general privacy notice displayed at registration. Hospitals should maintain a research-data portal that explains active categories of secondary use, governance bodies, commercial involvement, data-sharing partners, major results, and methods for exercising rights. Patient preferences can be recorded through a tiered system that distinguishes direct care, mandatory public-health functions, low-risk public-interest research, commercial research, recontact, and return of individual findings. Preference systems should be designed to avoid digital exclusion and must include offline assistance. Ethics committees may approve a waiver of consent only after examining necessity, minimal risk, impracticability, security, and the adequacy of public transparency.[45]

Commercial collaboration requires particular clarity. A patient's data or biological material may contribute to a profitable product even when the patient has no proprietary claim to the resulting intellectual property. The ethical issue is not resolved by stating this fact in small print. Hospitals should disclose material

[44] Republic of Indonesia, *Undang-Undang Nomor 27 Tahun 2022 tentang Pelindungan Data Pribadi*, Lembaran Negara Republik Indonesia Tahun 2022 Nomor 196, Tambahan Lembaran Negara Republik Indonesia Nomor 6820.

[45] Annabelle Cumyn et al., "Meta-Consent for the Secondary Use of Health Data within a Learning Health System: A Qualitative Study of the Public's Perspective," *BMC Medical Ethics* 22 (2021): 81, https://doi.org/10.1186/s12910-021-00647-x.

commercial relationships, prohibit undisclosed onward sale, ensure that access serves an approved purpose, and negotiate public or patient benefit where appropriate. Return of general results, affordable access strategies, capacity building, or reinvestment in patient services can form part of benefit-sharing. Research findings that reveal clinically significant information should be returned only after validation, professional interpretation, and a plan for counseling and follow-up.[46]

e. Compensation, Complaints, and Institutional Accountability

The fifth and sixth gates concern injury compensation and accountability. Hospitals hosting interventional research should require insurance, sponsor indemnity, or another secured fund sufficient for immediate treatment and reasonable compensation. The participant-facing system should operate on a no-fault-oriented basis for harm causally connected to research procedures or products. Negligence remains relevant to additional legal liability, but it should not be a precondition for urgent care. A multidisciplinary panel independent of the study team should assess causation using temporal relationship, biological plausibility, alternative causes, protocol compliance, and available safety evidence. Written reasons, review rights, and time limits are essential.[47]

Compensation should cover more than hospital bills when evidence supports broader loss. Recoverable categories may include necessary treatment, rehabilitation, transport, lost income, disability, and death-related support, subject to transparent standards. Reimbursement for participation expenses and payment for time should remain payable independently of an injury claim. The consent form should not describe payment as a waiver or settlement of future rights. Contracts among hospital, sponsor, investigator, and insurer must establish advance payment and recourse mechanisms so that a participant receives assistance without waiting

[46] Rosie Dobson et al., "Exploring Patient Perspectives on the Secondary Use of Their Personal Health Information: An Interview Study," *BMC Medical Informatics and Decision Making* 23 (2023): 66, https://doi.org/10.1186/s12911-023-02143-1.

[47] Matt Lamkin, "Avoiding Exploitation in Phase I Clinical Trials: More Than (Un)Just Compensation," *Journal of Law and the Biosciences* 5, no. 1 (2018): 169–206.

for an allocation dispute. Where causation is uncertain, interim funding for clinically necessary care should be available pending review.[48]

An independent complaint mechanism is equally important. Participants should be able to report coercion, privacy concerns, unsafe practice, nonpayment, or retaliation outside the research team. The hospital should designate a patient-research ombuds function with authority to access records, protect confidentiality, arrange urgent clinical action, and refer matters to the ethics committee, regulator, data-protection function, or law-enforcement body. Complaints must not affect ordinary treatment. Aggregate complaint data, protocol deviations, serious adverse events, consent-quality findings, and compensation decisions should be reviewed by the board and reported periodically in de-identified form. Accredited ethics review remains essential, but it should be connected to hospital governance rather than treated as an external certificate filed at study opening.[49]

Implementation should begin with a board-approved policy that applies to all departments, affiliated clinicians, sponsors, and external research organizations. The policy should define classification, site authorization, consent standards, data access, safety escalation, injury care, compensation, complaints, and closure. A central research office can maintain the registry and coordinate approvals, while clinical departments remain responsible for safe care. Staff training should be role-specific. Clinicians need to recognize research procedures and adverse events, investigators need consent and protocol competence, information-technology staff need research-data controls, and finance staff need rapid payment pathways. Periodic simulation of emergency unblinding, breach response, and participant complaints can test whether written procedures work.

The model also requires measurable indicators. Hospitals should monitor the proportion of projects correctly classified, time from submission to review, consent comprehension scores, withdrawal patterns, protocol deviations, serious

[48] Barbara E. Bierer, Sarah A. White, Luke Gelinas, and David H. Strauss, "Fair Payment and Just Benefits to Enhance Diversity in Clinical Research," *Journal of Clinical and Translational Science* 5 (2021): e159.

[49] Republic of Indonesia, Ministry of Health, *Peraturan Menteri Kesehatan Nomor 75 Tahun 2020 tentang Komite Etik Penelitian dan Pengembangan Kesehatan Nasional*, Berita Negara Republik Indonesia Tahun 2020 Nomor 1289.

adverse-event reporting time, data-access anomalies, complaint resolution, and compensation processing. Indicators should be interpreted carefully. A low complaint count may reflect effective protection or an inaccessible channel. High withdrawal rates may indicate burdensome procedures rather than participant unreliability. Independent audits and patient feedback can provide context. Findings should lead to corrective action, protocol amendment, staff retraining, or suspension where necessary. The Ministry of Health and the Food and Drug Authority can use standardized indicators to identify systemic risks across institutions.

Collaborative oversight should preserve clear mandates. The Ministry of Health can establish baseline hospital governance and national reporting standards. The Food and Drug Authority should supervise regulated clinical trials and safety reporting. National and institutional ethics bodies should maintain accreditation, review quality, and ethical guidance. Hospitals should control site readiness, clinical response, data systems, and patient-facing remedies. Sponsors must finance and monitor the protocol and disclose safety information. These responsibilities overlap by design, but overlap should produce verification rather than evasion. A memorandum or national technical standard can specify data exchange, escalation thresholds, confidentiality, and lead responsibility for joint inspections.

The model is complete only when protection survives institutional conflict. A sponsor's instruction cannot prevent a hospital from giving necessary care or stopping unsafe enrollment. An investigator's academic interest cannot override a participant's withdrawal. Ethics approval cannot legitimize a data use that exceeds the approved purpose or lacks adequate security. Contractual confidentiality cannot block legally required reporting of harm. The 2024 Declaration of Helsinki, ICH E6(R3), and WHO guidance support a participant-centered standard in which rights, safety, well-being, scientific validity, and reliable evidence are mutually reinforcing. Indonesian implementation should translate those principles into enforceable hospital controls, documented decisions, and accessible remedies.[50]

[50] World Health Organization, *Guidance for Best Practices for Clinical Trials* (Geneva: World Health Organization, 2024), https://www.who.int/publications/i/item/9789240097711; International Council for Harmonisation, *ICH E6(R3) Guideline for Good Clinical Practice* (Geneva: ICH, 2025).

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Table 1. Integrated Patient Protection Model for Research-Based Hospital Services

Component	Principal Risk	Required Hospital Control	Patient-Facing Safeguard
Activity classification	Research is presented as ordinary care or quality improvement	Research-Care Classification Panel, written reasons, and project registry	Clear notice of whether activities are care, research, or dual-use
Ethical and scientific review	Invalid design or disproportionate risk	Proportional ethics review, site-readiness verification, and amendment control	Independent review before recruitment and when material changes occur
Consent and comprehension	Therapeutic misunderstanding, coercion, or unread forms	Layered information, teach-back, independent verification, and re-consent	Understandable choices, refusal without loss of care, and effective withdrawal
Safety and continuity of care	Delayed treatment, incomplete adverse-event reporting, or unsafe continuation	Integrated safety reporting, emergency procedures, independent monitoring, and stop authority	Immediate care, follow-up, and continuity after withdrawal or study closure
Data governance	Unauthorized reuse, re-identification, breach, or opaque commercial access	Data mapping, minimization, access logs, impact assessment, contracts, and transparency portal	Meaningful information, preference choices, complaint access, and result communication
Compensation and accountability	Participants bear injury costs or are referred among institutions	Secured fund or insurance, no-fault-oriented assessment, ombuds function, audit, and public reporting	Rapid treatment, reasoned compensation decisions, review rights, and protection from retaliation

Source: Developed by the authors from the 2024 Declaration of Helsinki, ICH E6(R3), WHO clinical-trial guidance, and Indonesian health, clinical-trial, ethics, medical-record, and personal-data regulations.

D. Conclusion

Research-based hospital services create a dual legal relationship. The individual remains a patient entitled to safe, continuous, and non-discriminatory care while also becoming a research participant, data subject, or source of biological material when an activity seeks generalizable knowledge. Indonesian health, clinical-trial, ethics, medical-record, and data-protection rules contain substantial safeguards, but their separate operation can leave uncertainty at the transition points between care and research. The decisive protection task is therefore institutional integration. Hospitals must classify activities before implementation, distinguish standard care from protocol-driven procedures, and ensure that ethics or regulatory approval does not replace responsibility for clinical safety, data stewardship, and patient remedies.

The proposed Research-Based Hospital Patient Protection Model answers this problem through six connected gates: classification, proportional review,

layered consent, safety and continuity, data governance, and compensation with independent accountability. The model treats consent as communication verified by comprehension, not as a signature. It differentiates secondary data uses according to purpose and risk, requires immediate treatment for suspected research injury, and creates a single patient-facing complaint and compensation channel. Its governance structure preserves the mandates of the ethics committee, regulator, sponsor, investigator, and hospital while preventing participants from bearing the consequences of disputes among those actors.

The Ministry of Health should issue a national technical standard for embedded and dual-use research in hospitals, including classification criteria, minimum consent architecture, injury-care guarantees, compensation, and public reporting. Hospitals should establish classification panels, research ombuds functions, secured compensation arrangements, and integrated safety and data systems. The Food and Drug Authority should align clinical-trial inspection and adverse-event reporting with hospital patient-safety mechanisms. National and institutional ethics bodies should audit consent quality and continuing review, not merely initial documents. Sponsors should fund adequate insurance, post-trial commitments, and rapid treatment pathways. These measures would permit responsible research expansion while maintaining the patient's rights and welfare as the controlling institutional priority.

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