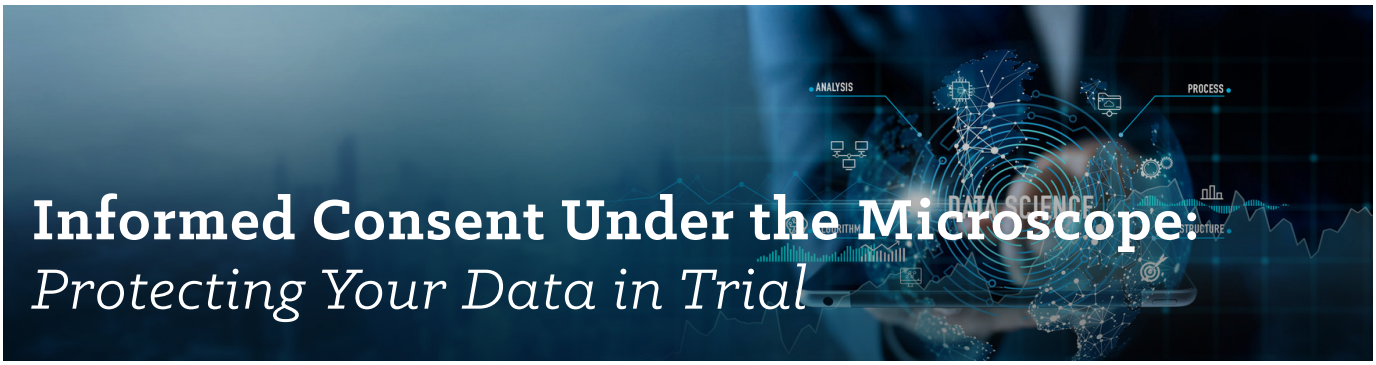
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Informed Consent Under the Microscope:
Protecting Your Data in Trial

A clinical trial is a structured research study involving human participants, designed to evaluate new tests, treatments, or interventions. Its purpose is to observe and assess health outcomes, providing critical evidence on safety and effectiveness.[1] Clinical trials are of paramount importance, serving as a crucial stage in translating laboratory findings into practical treatments that can improve patient care.

For clinical trials, the matter of informed consent is a foundational prerequisite for handling a participant's personal data. It requires the participants to be fully informed about the trial, including what personal data will be collected, how it will be used, protected and shared and who will have access to it.[2]

Definition and Core Principle

Informed consent is a process which trial participants voluntarily confirm their willingness to enroll in a specific trial, after receiving clear information about all relevant aspects of the trial that may influence their decision to participate.

The duty to obtain informed consent lies with the Investigator as laid out by the Malaysian Medical Council (MMC) Guideline on Clinical Trials and Biomedical Research. The guideline is grounded with three ethical principles: respect for persons, beneficence and justice. The principle of respect for persons necessitates the ethical obligation to secure informed consent from trial participants and to uphold the confidentiality of their personal information. The Investigator is ethically and professionally obligated to provide potential trial participants information about the trial's objectives, procedures, risks, benefits and their rights to refuse or withdraw at any time without a penalty. Informed consent must be voluntary and appropriately documented through a signed, dated and witnessed Informed Consent Form.[5,6]

In Malaysia, the Informed Consent Form must be approved by Independent Ethics Committee (IEC) of the research facility prior to obtaining consent from the trial participant.[7] A good Informed Consent Form should be written in a simple practical language and should be understandable to the trial participant. The IEC is also responsible for ensuring that the Informed Consent Form includes all pertinent information related to the clinical trial, including compensation for participant.[8]

This article explores the legal dimensions of consent and data governance in clinical trials.

Legal Frameworks Governing Personal Data in Clinical Trials

As Malaysia's role in global clinical trials grows, aligning domestic frameworks with international standards for informed consent and data protection is essential. This section examines Malaysia's legal ethical framework and its alignment to International Standards:

Malaysian Context:

Personal Data Protection Act 2010 and the 2024 Amendments

Personal Data Protection Act (PDPA) 2010 is the main legislation that governs how 'data users,' or 'data controllers,' (according to the 2024 amendments) are to handle personal data, including but not limited to information gathered in clinical trials. PDPA's relevancy for clinical research is growing since clinical trials increasingly rely on digital data systems, cross-border data transfers and developing technologies.

In the context of a clinical trial, the PDPA 2010 ensures that data is protected by requiring that:

- Data is collected only for a lawful purpose, paired with adequate notice given to participants about what data will be collected and how it will be used, similar to European Union's (EU) General Data Protection Regulation (GDPR).
- Sensitive personal data (such as health information) be handled delicately, ensuring participants understand what is being collected and how it is processed and disclosed.
- The data user operates with accountability: maintaining security safeguards, limiting retention of data and ensuring accuracy of the data.[9]

INTERNATIONAL CONTEXT

EU GDPR

The GDPR is a comprehensive legislative framework for the protection of personal data in Europe, with its provisions outlining rights of individuals and duties for organisation.[10] In the context of clinical trials, health data is classified as 'special categories,' of personal data under the GDPR (Article 9).

The processing of sensitive health data in clinical research is subject to stricter legal requirements under the GDPR. One of the most notable requirements is the need for explicit consent from participants as per Article 9. Article 4 (11) defined consent as 'any freely given, specific, informed and unambiguous indication of the data subject's wishes by a statement or by a clear affirmative action.'[11] This implies that participant information and permission forms must explicitly state how their health data will be used for the particular trial and the data controller must be able to prove that the consent was freely provided, explicit, informed and unambiguous.

Under the GDPR, clinical trials must follow key data protection principles, including data minimisation and purpose limitation. Data minimisation (Article 5(1)(c)) requires collecting only personal data that is adequate, relevant and necessary for conducting the trial, whereas purpose limitation (Article 5(1)(b)) requires that personal data be collected for specific, explicit and legitimate purposes relevant to the trial. The entity controlling the data (e.g. research sponsor) must be able to demonstrate compliance with all these requirements.

- **ICH-GCP E6(R3) (2025):**
  ICH-GCP E6(R3) is the global standard for clinical trial conduct and monitoring. It revolutionises clinical research through risk-based methods that enhance efficiency and data integrity. The importance of informed consent and protection of participants' rights remains a cemented core in this guideline, with Section 2, Principle 2 stating that:[12] 'Informed consent is an integral feature of the ethical conduct of a trial. Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed.'

- **Declaration of Helsinki (2024 Revision):**
  The Declaration of Helsinki provides globally referenced ethical guidelines for human research, mandating voluntary informed consent with clear information and no coercion. The significance of informed consent in clinical research is paramount as it aligns research practices with both ethical standards and legal protections.

SECTION 3. Recent Legal Updates on Personal Data and Informed Consent

In 2025, the ICH-GCP E6 (R3) has acknowledged significant advancements in clinical trial methodologies and technologies since the previous E6 (R2) iteration. ICH-GCP E6 (R3) provides guidance on the integration of electronic records, remote monitoring and digital health technologies including digital consenting to adapt and streamlined consent process. Additionally, the revision introduces more stringent requirements for data security, audit trails and traceability, hereby ensuring that electronic and remotely collected trial data adhere to high-quality standards.[13,14]

In 2024, the Declaration of Helsinki introduces significant updates on broad consent. Broad consent allows participants to give a single informed consent for the future bona fide research.[17] Paragraph 32 of the Declaration has been rewritten to address informed consent requirements for collecting, storing and secondary use of data and biological materials. Moreover, the Declaration recognised the integration of digital technologies in clinical trials including electronic informed consent (e-Consent). The validation of e-Consent reflects its evolution from a mere alternative to an increasingly standard practice which support to enhance participant comprehension, engagement and accessibility within the clinical trial process.

The National Committee for Clinical Research endorsed the Malaysia Decentralised Clinical Trial Guidance Document in 2023, which outlines the implementation of e-Consent. The e-Consent process should follow the PDPA and relevant regulation. It must convey clear and concise information regarding the trial, including its objectives, potential risks and benefits and measures to ensure participant confidentiality. From a technological standpoint, the e-Consent interface should be designed to be user-friendly, intuitive and easily navigable which allow participants to pose questions and seek clarification prior to providing consent. They also should be given the option to withdraw their e-Consent easily. The entire process must be thoroughly documented and securely stored for the duration of the trial, ensuring that it remains accessible and auditable for regulatory inspections or reviews.[18]

Section 4. Implementation Insights

The PDPA serves as the principal legislative framework governing the protection of personal data within the Malaysian healthcare sector. The PDPA establishes consent as a legally recognised basis for the lawful processing of health-related information. Pursuant to Section 6 of the PDPA, data processing is permitted solely for legitimate purposes that are directly connected to the activities of the data user while Section 40 sets out the conditions under which sensitive personal data, including health information, may be processed. The PDPA takes a flexible approach to consent, allowing its application to be adapted to different contexts. Consequently, institutions may adopt varying methods of obtaining patient consent, with many favouring written consent to support clarity and accountability.

In the context of big data, rapid advancements in technologies such as data mining and profiling make it difficult to predict future uses of personal data. For instance, patients may initially consent to their data being used for treatment and research within the company. However, as technology evolves the company may begin to apply advanced profiling techniques to predict health risks and share insights with third party insurers.

Sections 30 to 44 of the PDPA require company to safeguard personal data and obtain valid consent for its processing. Such scenarios illustrate the practical challenges of applying consent based protections in a rapidly evolving technological environment, particularly where data reuse and secondary analysis are involved.[19]

Globally, the EU has implemented the GDPR to enhance data privacy protections. In 2020, the EU issued a policy document entitled Big Data and Artificial Intelligence, which highlights both the significant opportunities and the complex challenges associated with the utilisation of large-scale data in healthcare. However, the practical of GDPR implementation remains a subject of discussion. Lalova-Spinks et al. (2022) reports that ethics committees (ECs) often advise on the legal basis for data processing. While guidance may assist compliance, enforcing such opinions would contradict GDPR's accountability principle, which assigns full responsibility to the data controller as data controllers are required to ensure and demonstrate compliance with data protection laws, the determination of the appropriate legal basis for data processing should therefore remain exclusively with the data controller.[20]

In the context of cross-border clinical trials, determining a uniform legal basis for data processing under the GDPR remains a mission. The use of disparate legal bases within cross-border study risks creating inconsistencies in the protection afforded to data subjects, thereby leading to unequal treatment of participants.[21] Notably, European Commission's assessment study reveals that 'the understanding and application of consent can vary significantly across Member States,'[22] highlighting the need for further legal clarification and interpretative consistency regarding the role of consent within the GDPR framework.[23]

Analysis and Recommendations

Informed consent has evolved into a legal and ethical requirement protecting individual control over personal data and participant autonomy in research.

Malaysia's PDPA balances commercial interests with privacy, GDPR sets the global data protection benchmark and ICH GCP establishes international ethical standards for clinical research.

The PDPA, the EU GDPR, and the ICH GCP guidelines, each address informed consent within the context of their respective objectives, while sharing a common emphasis on individual autonomy. The PDPA focuses on the use of personal data in commercial and organisational settings, allowing consent to be given either explicitly or impliedly through reasonable actions and providing individuals with right to access and correct their data...[24] The GDPR reflects a detailed and structured approach to informed consent, setting clear requirements for how consent is obtained and managed, including that it must be

specific, informed and unambiguous, with particular attention to sensitive data and straightforward mechanisms for withdrawal.[25] The ICH GCP guidelines, though not a legislative instrument, extend the principle of informed consent beyond data protection into the ethical domain of clinical research, mandating written, voluntary and fully informed agreements that safeguard participants' welfare and allows withdrawal at any stage without penalty.[26]

The Malaysian judiciary has played a formative role in shaping the doctrine of informed consent. In Foo Fio Na v Dr Soo Fook Mun & Anor [2007] 1 MLJ 593, the Federal Court adopted the 'reasonable patient,' standard, holding that a physician's failure to disclose material risks constituted a breach of duty.[27] This landmark case underscores the legal importance of transparency and disclosure in medical decision-making, aligning Malaysian jurisprudence with international norms of patient autonomy.

Within the European Union, the GDPR has been interpreted and enforced with rigor in the health research domain. The European Data Protection Board (EDPB) clarified in its Guidelines 03/2019 that processing health data for scientific research may be justified under the lawful basis of public interest, provided that appropriate safeguards are implemented.[28] Enforcement practice further illustrates the GDPR's strength in 2021, the Hellenic Data Protection Authority fined a hospital for relying on invalid consent, demonstrating the regulation's capacity to impose significant penalties for non-compliance.[29]

Globally, informed consent obligations are reinforced through both ethical and legal mechanisms. In Singapore, the Health Sciences Authority suspended a clinical trial due to non-compliance with GCP documentation standards, highlighting the operational importance of proper consent procedures.[30]

Therefore, several forward-looking reforms are recommended to further strengthen the coherence and enforceability of informed consent regimes. The Malaysian PDPA can be enhanced with health-specific provisions, dynamic consent mechanisms and expand data subject rights, thereby advancing protection in research context.[31] Embedding ICH GCP ethical standards into statutory law would further enhance enforceability and promote consistent clinical research practice. For example, under ICH GCP E6(R2), and reaffirmed in E6(R3), informed consent must be obtained prospectively and re obtained when new safety information becomes available. Statutory codification of these requirements would transform such obligations from guidance based expectations into legally binding duties, thereby strengthening accountability and aligning Malaysia's regulatory framework with internationally harmonised standards (ICH E6(R2), 2016; ICH E6(R3), 2025).[32] Greater legal oversight, targeted training for Ethics Committees and Investigators on informed consent would help to ensure that informed consent processes meets legal, ethical and data security standards. On a cross-border level, adequacy frameworks and bilateral agreements would serve as practical mechanism to facilitate lawful international data transfers while safeguarding participant rights.[33] Finally, investment in secure digital infrastructures with audit trails would provide a transparent and accountable system for documenting consent and managing sensitive health data.[34] This includes implementing end-to-end encryption, secure data transmission and storage systems that protect unauthorised access or alteration of consent records.

Collectively, these measures would further strengthen the alignment of Malaysia's data protection and research ethics frameworks together with global best practices, ensuring that informed consent remains both a legal safeguard and an ethical cornerstone in clinical trial settings.

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