

Clinical Research Governance in Malaysian Hospitals: A Maqāsid Al-Sharī'ah Perspective and Comparative Analysis of Bioethical Principlism

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ABSTRACT

Clinical research is essential to the progress of modern medicine, especially in developing safe and effective therapies, pharmaceuticals, and health technologies. Ethical oversight of clinical trials is largely shaped by international frameworks such as ICH Good Clinical Practice (E6[R3]) and national standards including the Malaysian Guideline for Good Clinical Practice (4th Edition). Together, these frameworks prioritize participant protection, scientific integrity, informed consent, and institutional accountability. In Muslim-majority settings such as Malaysia, ethical appraisal of hospital-based research may be strengthened by a complementary normative lens grounded in Maqāsid al-Sharī'ah (the objectives of Islamic law). This article offers a conceptual analysis of clinical research ethics in hospital environments through Maqāsid reasoning while critically engaging Western bioethical principlism. Using a qualitative, library-based approach, the study synthesizes classical and contemporary Maqāsid scholarship alongside regulatory and healthcare ethics literature. The analysis indicates that the preservation of life (*hifz al-nafs*), intellect (*hifz al-'aql*), wealth (*hifz al-māl*), lineage (*hifz al-nasl*), and religion (*hifz al-dīn*), supported by the pursuit of maṣlaḥah (public benefit) and the prevention of mafsadah (harm), provides a holistic and purpose-oriented ethical framework. Beyond aligning with global governance standards, the Maqāsid approach adds ethical depth by emphasizing moral intention, spiritual accountability, and socio-communal welfare. Integrating Maqāsid into Malaysian clinical research governance may therefore enhance ethical robustness while remaining compatible with international regulatory expectations. This paper proposes a two-layer framework for IRB deliberation that maintains GCP requirements while incorporating Maqāsid-oriented ethical considerations for Malaysian hospital governance.

Keywords: Clinical research; Good Clinical Practice; Hospital; Islamic medical ethics; Maqāsid al-Sharī'ah.

INTRODUCTION

The development of modern medical science depends on systematic, methodologically sound, and ethically regulated clinical research (Abdulah Hashi, 2022). Clinical trials underpin evidence-based medicine by generating data on safety, efficacy, dosage, long-term outcomes, and comparative effectiveness of medicines, devices, diagnostics, and therapeutic interventions before they are adopted into routine care (International Council for Harmonisation [ICH], 2025). Without structured research involving human participants, therapeutic innovation would lack empirical validation and regulatory credibility.

Hospitals represent the primary institutional setting for clinical research due to established infrastructure, multidisciplinary expertise, ethics oversight, and access to diverse patient populations. In hospital contexts, research often occurs alongside active clinical care, producing an ethically complex environment in which patients may be both treatment recipients and research participants. This overlap heightens the need for transparency, stringent governance, and professional responsibility (Abdulah Hashi, 2022).

Although indispensable, clinical research carries ethical risks. Past abuses in human experimentation demonstrate how vulnerable groups can be exposed to exploitation, coercion, or deception when oversight is weak. Such failures prompted the creation of international standards centred on human dignity and participant protection. Accordingly, ICH Good Clinical Practice emphasizes that the rights, safety, and well-being of participants must take precedence over scientific and societal interests (ICH, 2025). Likewise, the Malaysian Guideline for Good Clinical Practice requires independent ethics review, voluntary informed consent, confidentiality safeguards, and scientifically justified protocols (National Pharmaceutical Regulatory Agency [NPRA], 2018).

Ethical conduct in clinical research is reinforced by broader global guidance. The WHO Handbook for Good Clinical Research Practice stresses that trials must be scientifically credible and implemented under recognized ethical and quality standards to protect participant rights, safety, and welfare (World Health Organization [WHO], 2005). Key elements include independent review, meaningful consent, risk–benefit evaluation, competent investigators, and robust quality systems. Complementing this operational guidance, CIOMS ethical guidelines provide normative principles grounded in respect for persons, beneficence, and justice, with attention to vulnerability, fair distribution of burdens and benefits, and sponsor obligations—particularly in low-resource contexts (Council for International Organizations of Medical Sciences [CIOMS], 2016).

Malaysia participates in internationally harmonized research governance while also functioning as a Muslim-majority country with growing institutional interest in Shariah-compliant healthcare (Mohd Noor & Mohd Noor, 2021). Its healthcare landscape spans public and private sectors, includes medical tourism initiatives, and increasingly engages ethical debates informed by Islamic values. Malaysian scholarship has likewise highlighted Maqāṣid al-Sharī‘ah as a relevant framework for contemporary biomedical decision-making (Rosman et al., 2019). This dual regulatory–religious setting raises a normative question: while GCP ensures procedural safeguards and operational compliance, does it adequately reflect Islamic ethical philosophy in hospital-based research environments?

From an Islamic ethical standpoint, healthcare is not merely technical practice, but a moral enterprise aimed at realizing benefit (*maṣlaḥah*) and preventing harm (*mafsadah*) for individuals and society (Abdulah Hashi, 2019; Rosman et al., 2019). Maqāṣid al-Sharī‘ah articulates a purposive framework oriented toward the preservation of life (*ḥifẓ al-naḥs*), intellect (*ḥifẓ al-‘aql*), wealth (*ḥifẓ al-māl*), lineage (*ḥifẓ al-nasl*), and religion (*ḥifẓ al-dīn*). These objectives extend evaluation beyond procedural compliance to include comprehensive welfare, moral intention, and spiritual accountability (Abdulah Hashi, 2019). In classical and contemporary Maqāṣid theory, ethical reasoning is not confined to rule-compliance but is directed toward the higher purposes (maqāṣid) that secure comprehensive human welfare and social flourishing. Ibn ‘Āshūr’s purposive reformulation emphasizes that Sharī‘ah aims at sustaining order, justice, and well-being through an objective-driven jurisprudence rather than legal formalism alone (Ibn ‘Āshūr, 2006). Al-Raysūnī further clarifies that *maṣlaḥah* is central to maqāṣid reasoning and must be assessed through structured prioritization and contextual evaluation (al-Raysūnī, 2005). In modern applications, Auda’s “systems approach” highlights interconnectedness, openness to context, multi-dimensionality, and outcome-orientation, which are particularly relevant to complex institutional settings such as hospitals and clinical research governance (Auda, 2008). These frameworks support the view that Maqāṣid can complement procedural research ethics by offering an additional layer of purposive evaluation grounded in justice, public good, and long-term consequences.

Recent work in Islamic medical ethics also emphasizes incorporating Maqāṣid reasoning into healthcare governance, including institutional policies and hospital standards (Mohd Noor & Mohd Noor, 2021). Emerging technologies—such as AI in healthcare—introduce additional ethical complexity, requiring frameworks capable of balancing innovation with justice, equity, and harm prevention (Yunos & Hamdan, 2024). Such developments strengthen the case for an ethical paradigm that is globally compatible yet locally resonant within Malaysia’s socio-religious context.

Accordingly, this study presents a conceptual analysis of hospital-based clinical research through Maqāṣid al-Sharī‘ah while critically engaging Western bioethical principlism. Rather than replacing established regulatory structures, the article explores how Maqāṣid can enrich existing governance by embedding procedural

safeguards within a broader moral purpose. By situating international standards alongside Islamic normative philosophy, the study contributes to discussions on ethically plural and culturally responsive healthcare governance in Malaysia.

RESEARCH METHODOLOGY

This study adopts a qualitative conceptual and normative-analytical design grounded in library-based research. Rather than conducting empirical fieldwork, it undertakes a structured theoretical examination of hospital-based clinical research ethics through a comparative and integrative framework. Conceptual analysis is particularly appropriate in bioethical scholarship, where the objective is not to measure behavioural outcomes but to clarify normative foundations, interpret ethical principles, and evaluate the coherence of governance frameworks.

The study operates within a normative-constructive paradigm. It does not aim to test institutional performance or empirical compliance levels; instead, it interrogates the ethical architecture underlying clinical research governance and explores how Maqāṣid al-Sharī‘ah may function as a complementary evaluative lens. In this sense, the research aligns with philosophical bioethics and jurisprudential analysis, where the primary task is critical reflection on principles, values, and moral reasoning rather than statistical generalization.

Primary regulatory sources include ICH E6(R3), the Malaysian Guideline for Good Clinical Practice (4th Edition), and major international ethics instruments such as the WHO Handbook for Good Clinical Research Practice and the CIOMS Guidelines. These documents are analyzed descriptively to identify their core ethical assumptions and procedural commitments. In parallel, classical and contemporary Maqāṣid literature—including works by Ibn ‘Ashūr, al-Raysūnī, and Jasser Auda—are examined to reconstruct Maqāṣid as a coherent purposive ethical framework.

The analytical process proceeds in three interconnected stages:

1. **Descriptive analysis** – mapping the normative foundations and governance structures embedded within contemporary clinical research regulation.
2. **Normative reconstruction** – articulating Maqāṣid al-Sharī‘ah as a systematic ethical paradigm grounded in teleology, *maṣlahah*–*mafsadah* balancing, and the five essential objectives.
3. **Comparative evaluation** – identifying convergences, divergences, and areas of complementarity between Western principlism and Maqāṣid-based reasoning within Malaysia’s regulatory and socio-religious context.

This design reflects an approach of ethical pluralism, where universal procedural standards are critically engaged alongside culturally grounded moral reasoning. The study does not propose regulatory replacement but normative enrichment—examining how existing governance structures may be interpreted through an additional purposive ethical lens without undermining international harmonization.

The scope of this research is confined to conceptual analysis of governance frameworks rather than empirical evaluation of institutional implementation. Malaysia is selected as the focal context due to its dual regulatory–religious environment, where internationally harmonized biomedical governance coexists with expanding discourse on Shariah-compliant healthcare systems. Future research may incorporate empirical methods—such as interviews with IRB members or case-based institutional analysis—to assess practical feasibility and impact of Maqāṣid-informed governance.

Clinical Research In Modern Healthcare

Clinical research refers to systematic investigation involving human participants to generate generalizable medical knowledge and improve health outcomes (Abdulahi Hashi, 2022). In modern health systems, it forms

the empirical basis of evidence-based medicine by ensuring that medicines, devices, diagnostics, and therapeutic protocols are evaluated through structured processes before broad clinical adoption (ICH, 2025).

Clinical trials commonly proceed through phased designs intended to manage risk while strengthening evidence. Phase I focuses on safety, dose range, and pharmacokinetics in small cohorts. Phases II and III expand recruitment to establish efficacy and comparative effectiveness. Phase IV, conducted after marketing authorization, monitors longer-term safety and real-world effectiveness (ICH, 2025). This staged approach reflects incremental risk control that aims to protect participants while supporting innovation.

Ethical governance is anchored by safeguards that have been standardized globally through Good Clinical Practice (GCP): risk–benefit proportionality, independent ethics review, voluntary informed consent, confidentiality and data protection, qualified research teams, and continuous safety monitoring including adverse event reporting and data safety oversight (ICH, 2025; NPRA, 2018). Collectively, these elements reflect the bioethical orientation commonly framed through autonomy, beneficence, non-maleficence, and justice.

In hospital environments, ethical complexity increases. Trials often enrol patients receiving active care for serious illnesses, which may create dependency dynamics between clinicians and patients. This setting heightens the risk of therapeutic misconception—where participants incorrectly assume research participation guarantees individualized treatment benefits rather than contributing primarily to generalizable knowledge (Abdulahi Hashi, 2022). Such misconceptions can blur the boundary between clinical care and research aims.

Compensation mechanisms, while intended to reimburse costs or inconvenience, may also influence economically vulnerable individuals. In resource-limited contexts, incentives can shift from reimbursement to undue inducement, undermining voluntariness. While ethics committees and documentation requirements attempt to reduce this risk, socio-economic disparities remain a persistent governance challenge (NPRA, 2018).

Although global standards provide robust procedural protections, their normative orientation is largely secular and autonomy centred. Ethical legitimacy is often articulated through consent, compliance, and risk minimization (Abdulahi Hashi, 2019). In Muslim-majority settings such as Malaysia, where Shariah-compliant governance is increasingly discussed, ethical deliberation may reasonably extend to moral intention (*niyyah*), communal benefit (*maṣlahah*), and harm prevention (*mafsadah*) (Mohd Noor & Mohd Noor, 2021; Rosman et al., 2019). Viewed in this way, Maqāṣid al-Sharī‘ah functions as a complementary lens that strengthens ethical interpretation without displacing existing GCP requirements (Rosman et al., 2019).

Regulatory Foundations In Malaysia

ICH E6(R3) and Ethical Governance

ICH E6(R3) is a leading internationally harmonized guideline governing the design, conduct, monitoring, auditing, recording, analysis, and reporting of clinical trials involving human participants (ICH, 2025). Its purpose is to standardize scientific rigor and ethical safeguards across jurisdictions, thereby supporting public confidence in biomedical research.

A central ethical commitment in ICH E6(R3) is the primacy of participant welfare: the rights, safety, and well-being of participants must supersede the interests of science and society (ICH, 2025). This commitment parallels major international ethical traditions, including the Declaration of Helsinki, and reflects the evolution of research ethics following historical abuses (World Medical Association, 2024).

The guideline also emphasizes scientifically justified protocols, proportional risk assessment, independent ethics review through IRB/IEC mechanisms, quality management systems, documentation integrity, transparency, and adverse event reporting (ICH, 2025). The R3 revision further strengthens governance by embedding risk-based oversight and quality-by-design approaches across the trial lifecycle, ensuring that ethical safeguards are integrated rather than treated as administrative formality.

Nevertheless, while ICH provides operational robustness and global harmonization, its ethical framing remains largely secular and autonomy centred. Concepts such as communal welfare, spiritual accountability, and teleological moral purpose are not explicitly foregrounded within the framework.

Malaysian Guideline for Good Clinical Practice

The Malaysian Guideline for Good Clinical Practice (4th Edition) contextualizes ICH standards within national regulation under the NPRA (NPRA, 2018). It remains closely aligned with global principles but includes administrative requirements and local considerations relevant to Malaysia's healthcare environment.

Key emphases include confidentiality protections, mandatory ethics approval, comprehensive consent documentation (including clarity and comprehension), investigator competence, and cultural sensitivity within Malaysia's multi-religious society (NPRA, 2018). At the same time, Malaysia's healthcare landscape includes public and private sectors, medical tourism, and an expanding discourse on Shariah-compliant institutional frameworks (Mohd Noor & Mohd Noor, 2021). These realities create ethical expectations that extend beyond procedural compliance.

For many Muslim participants, ethical acceptability may involve religious permissibility, sincerity of intention, and contribution to public benefit (*maṣlahah*). Malaysian scholarship increasingly argues that Maqāṣid reasoning can provide a coherent framework to enrich governance by linking clinical research ethics to Islamic objectives and moral accountability (Rosman et al., 2019). Thus, Maqāṣid integration is best framed as normative enrichment rather than regulatory replacement, preserving harmonization while strengthening cultural resonance (Rosman et al., 2019).

Maqāṣid Al-Sharī'ah: A Normative Ethical Framework

Maqāṣid al-Sharī'ah denotes the higher purposes of Islamic law oriented toward realizing welfare (*maṣlahah*) and preventing harm (*mafsadah*) at individual and collective levels (Rosman et al., 2019; Jabatan Mufti Wilayah Persekutuan, 2019). It articulates a purposive jurisprudential philosophy that prioritizes substantive moral outcomes rather than rigid formalism (Abdulah Hashi, 2019). Within the Maqāṣid tradition, purposive reasoning is commonly operationalized through an evaluation of ends (*ghāyāt*), means (*wasā'il*), and consequences (*ma'ālāt*), ensuring that ethical judgments remain sensitive to context while preserving core objectives (al-Raysūnī, 2005; Auda, 2008). This approach aligns with Ibn 'Āshūr's emphasis on law as a moral-teleological enterprise aimed at securing welfare and preventing systemic harm, especially within public institutions (Ibn 'Āshūr, 2006). As a result, Maqāṣid ethics provides a structured normative grammar for linking biomedical innovation to justice, dignity, and public responsibility—dimensions often treated as secondary to procedural compliance in operational guidelines.

Classical formulations identify five essentials (*al-ḍarūriyyāt al-khams*): preservation of religion (*ḥifẓ al-dīn*), life (*ḥifẓ al-naḥs*), intellect (*ḥifẓ al-'aql*), lineage (*ḥifẓ al-nasl*), and wealth (*ḥifẓ al-māl*) (Abdul Halim & Ismail, 2024; Rosman et al., 2019). In contemporary Islamic medical ethics, these essentials function as applied criteria that guide clinical practice, institutional governance, and biomedical innovation.

Unlike purely procedural ethics, Maqāṣid evaluates actions teleologically—by examining their ultimate implications for holistic human welfare and social flourishing (Abdulah Hashi, 2019). Ethical legitimacy is therefore not limited to compliance but also includes alignment with justice, compassion, proportionality, and purposeful benefit.

Maqāṣid-based ethics integrates moral intention (*niyyah*), communal responsibility, accountability before God, and long-term consequences into ethical deliberation (Rosman et al., 2019). It is also adaptive: through *ijtihad* and contextual reasoning, Maqāṣid is applied to emerging biomedical issues—including transplantation, reproductive technologies, genetic interventions, and AI—through structured harm-benefit evaluation (Yunos & Hamdan, 2024). In clinical research, this framework complements GCP by adding moral purpose and broader justice considerations to procedural safeguards.

Maqāsid-Based Analysis Of Clinical Research

A Maqāsid approach does not dismiss established safeguards; rather, it situates them within a purposive moral horizon directed toward comprehensive human welfare. Each essential objective provides an evaluative lens for research practice in hospital settings (Rosman et al., 2019).

Preservation of Life (*Hifẓ al-Nafs*)

Clinical research is ethically justified when it meaningfully protects and advances life through improved prevention, diagnosis, and treatment (Abdulah Hashi, 2022). Maqāsid nevertheless requires proportionality: life preservation cannot be pursued through excessive or unnecessary risk. While GCP mandates risk–benefit assessment, Maqāsid strengthens this evaluation by emphasizing necessity (*darūrah*) and the absence of safer alternatives. Research driven primarily by commercial motivations without substantial medical value would therefore be ethically weak under Maqāsid reasoning (Rosman et al., 2019).

Preservation of Intellect (*Hifẓ al-‘Aql*)

Hifẓ al-‘aql reinforces the ethical core of informed consent: participants must receive truthful, comprehensible information enabling rational decision-making (NPRA, 2018). Deception, coercion, or manipulation undermines both regulatory ethics and Maqāsid commitments. While Western frameworks often frame consent in autonomy terms, Maqāsid links consent to moral accountability and sincerity. It also demands special protections against therapeutic misconception, especially in hospital contexts where clinical authority can distort participant understanding (Abdulah Hashi, 2019; Abdulahi Hashi, 2022).

Preservation of Wealth (*Hifẓ al-Māl*)

Compensation and contractual arrangements must avoid exploitation of socio-economically vulnerable participants. Undue inducement can compromise voluntariness and distort judgment, conflicting with justice (*‘adl*) and fairness embedded in *hifẓ al-māl*. Maqāsid further requires transparent sponsor–site contracts, appropriate indemnity and insurance, and ethical payment models aligned with legitimate scientific aims rather than profit-centered priorities (Rosman et al., 2019).

Preservation of Lineage (*Hifẓ al-Nasl*)

Research involving reproduction, genetics, stem-cell applications, or heritable interventions demands heightened scrutiny because it may affect family integrity and intergenerational outcomes. Maqāsid does not imply blanket prohibition, but it requires structured harm–benefit balancing attentive to long-term familial and societal implications, rather than treating technological feasibility as sufficient justification (Abdul Halim & Ismail, 2024).

Preservation of Religion (*Hifẓ al-Dīn*)

Hospital research in Muslim-majority settings should respect religious obligations, modesty norms, dietary requirements, and spiritual needs. *Hifẓ al-dīn* frames religion as an essential dimension of dignity and identity. Protocols that disregard these sensitivities may undermine participant trust and moral comfort even if procedural protections are met (Rosman et al., 2019; Mohd Noor & Mohd Noor, 2021).

Maṣlahah–Mafsadah Balancing

Maqāsid reasoning centers on weighing public benefit (*maṣlahah*) against potential harm (*mafsadah*). It accepts that some risk may be tolerated when justified by substantial public health value and when essential protections are not violated. While aligned with GCP risk–benefit logic, Maqāsid broadens assessment to include justice, long-term welfare, and moral purpose, thereby offering a principled method for resolving complex ethical dilemmas in hospital-based research (Rosman et al., 2019). In addition, a systems-oriented Maqāsid framing encourages evaluators to consider institutional dynamics—such as structural vulnerability,

information asymmetry, and long-term societal outcomes—rather than focusing solely on individual consent events or narrow biomedical endpoints (Auda, 2008; al-Raysūnī, 2005).

Comparative Perspective: Western Bioethics And Maqāsid

Western bioethics and Maqāsid al-Sharī‘ah differ in basis, autonomy, risk assessment, justice, oversight, epistemology, moral anthropology, and ontology of welfare. These distinctions are highlighted in Table 1. Principlism—autonomy, beneficence, non-maleficence, and justice—is a shared foundation of Western bioethics and influences clinical ethics and research governance globally. These guidelines support consent requirements, risk reduction, equitable participant selection, and IRB/IEC review monitoring in research settings (ICH, 2025; NPRA, 2018).

Table 1: Comparative Framework

Dimension	Western Bioethics	Maqāsid al-Sharī‘ah
Foundation	Secular principlism	Divine teleology
Autonomy	Individual self-determination	Rational choice with moral accountability
Risk	Harm minimization	Harm prevention + necessity (ḍarūrah)
Justice	Fair subject selection	Socio-economic equity and moral justice
Oversight	IRB/IEC procedural review	IRB + ethical-spiritual governance
Epistemological Basis	Secular moral rationalism	Revelation-informed teleology
Moral Anthropology	Autonomous rights-bearing individual	Morally accountable agent within divine and communal order
Ontology of Welfare	Biomedical and distributive	Holistic (spiritual, moral, communal, intergenerational)

Principlism is primarily secular and rights-based, and it usually bases legitimacy on procedural justice, rational consent, and harm reduction, even though it works well for harmonization. Similar issues are addressed by Maqāsid, but they are placed within a theocentric and purposeful worldview that is focused on divine accountability and the welfare of the community (Rosman et al., 2019).

For instance, Maqāsid acknowledges autonomy, but it frames it as moral obligation-based responsible choice rather than complete self-determination (Abdulahi Hashi, 2019). According to Rosman et al. (2019), risk assessment is in line with non-maleficence but is further organized by necessity (ḍarūrah): harm is only allowed when it is necessary to attain higher essential benefit and when less damaging options are not available. Justice is strongly related to *hifḍ al-māl* and goes beyond fair selection to include socioeconomic equity and protection against exploitation (Abdulahi Hashi, 2022). In addition to procedural assessment, oversight encompasses morally significant ethical culture and intention (*niyyah*) (Mohd Noor & Mohd Noor, 2021).

The divergence between Maqāsid al-Sharī‘ah and Western bioethics implies underlying anthropological and epistemological issues in addition to variations in applied principles. Western principlism is primarily based in secular moral philosophy and draws from consequentialist harm-reduction theories, liberal individualism, and Kantian autonomy, especially as it developed in late twentieth-century bioethics. In a pluralistic society, rational consideration, procedural justice, and rights-based reasoning are usually the sources of normative legitimacy.

Maqāṣid al-Sharī‘ah, on the other hand, is based on a moral epistemology guided by revelation. Ethical normativity is thought to be geared toward divinely planned objectives that assure human flourishing rather than being exclusively produced through philosophical argument or societal consensus. Although rational reasoning (*‘aql*) is still important, it functions within a teleological framework in which revelation establishes the hierarchy of values and offers ultimate moral guidance. As a result, ethical analysis goes beyond procedural legitimacy to encompass accountability before God and alignment with higher moral purposes (*ghāyāt*).

Different views of the human person result from this epistemic diversity. The individual is frequently portrayed in Western bioethics as an independent, rights-bearing entity. According to Maqāṣid thinking, the human being is immersed in family, community, and divine obligation while yet being autonomous and morally responsible (*mukallaf*). Therefore, autonomy is not ultimate self-determination but rather relational and goal oriented.

The ontology of welfare also varies little but considerably. Benefit and harm are often assessed using distributive fairness, biomedical measurements, and quality-of-life factors in Western research ethics. Maqāṣid broadens the definition of wellbeing to encompass communal cohesion, intergenerational stability, moral dignity, and spiritual integrity. For instance, the preservation of religion (*hifḍ al-dīn*) and ancestry (*hifḍ al-nasl*) offer aspects of ethical concern that are not usually highlighted in models of secular governance.

Incompatibility is not implied by these differences. Instead, they contend that Maqāṣid provides a teleological expansion of principlism. Maqāṣid provides purposive guidance, whereas Western bioethics ensures procedural validity. Thus, it is possible to view the two frameworks as functioning at complementary analytical levels: one protects operational fairness and regulatory compliance, while the other integrates those protections into a more expansive moral framework.

In general, Maqāṣid does not always contradict Western bioethics. Alternatively, it can serve as normative enrichment: Maqāṣid adds moral depth by combining purpose, spirituality, and collective responsibility, while GCP offers operational protections for harmonization (Rosman et al., 2019).

Implications For Malaysian Clinical Governance

Enhancing IRB Ethical Deliberation

IRBs typically evaluate proposals through risk–benefit analysis, consent adequacy, and scientific validity (ICH, 2025). Incorporating Maqāṣid reasoning can broaden deliberation to include long-term societal consequences, proportionality informed by necessity, and protection of socio-economically vulnerable groups—without altering procedural requirements (Rosman et al., 2019).

Providing Culturally Sensitive Ethical Guidance

Given Malaysia’s multi-religious society with a Muslim majority, ethical sensitivity to modesty, worship schedules, and dietary requirements may influence trust and participation (Mohd Noor & Mohd Noor, 2021). A Maqāṣid-informed approach supports culturally attuned governance, particularly in areas such as reproductive, genetic, and end-of-life research where religious concerns shape public perception (Abdul Halim & Ismail, 2024).

Strengthening Trust Among Muslim Participants

Public trust is central to ethical research. When governance aligns with participants’ moral worldview, perceived legitimacy and willingness to participate may increase. Maqāṣid emphasizes justice, anti-exploitation, and communal welfare—values that can reinforce transparency and confidence in hospital settings where vulnerability and therapeutic misconception may arise (Rosman et al., 2019; Abdulahi Hashi, 2022).

Adding Moral Depth to Compliance

GCP ensures documentation, data integrity, and accountability (ICH, 2025). Maqāṣid complements this by connecting ethical conduct to intention (*niyyah*), spiritual accountability, and long-term welfare, reframing governance as moral responsibility rather than administrative compliance alone (Abdulah Hashi, 2019).

Supporting Shariah-Compliant Healthcare Institutionalization

Malaysia's institutional discourse on Shariah-compliant hospitals increasingly extends beyond service delivery to governance culture (Mohd Noor & Mohd Noor, 2021). Extending Maqāṣid reasoning into research governance aligns hospital research practices with national socio-religious realities while maintaining international credibility (Rosman et al., 2019).

Proposed Maqāṣid-Informed IRB Integration Model for Malaysian Hospitals

While this study is conceptual in scope, its normative analysis permits the formulation of a structured integration model suitable for Institutional Review Board (IRB) deliberation within Malaysian hospital settings. The proposed model does not replace existing Good Clinical Practice (GCP) procedures; rather, it supplements them by embedding teleological ethical evaluation alongside procedural safeguards.

The model operates as a dual-layer governance structure:

Layer 1: Procedural Compliance (Existing GCP Framework)

- Scientific validity of protocol
- Risk–benefit proportionality
- Informed consent adequacy
- Confidentiality and data protection
- Investigator qualification and accountability
- Independent IRB review

These elements remain mandatory under ICH E6(R3) and Malaysian GCP standards.

Layer 2: Maqāṣid-Based Ethical Deliberation (Normative Enrichment Layer)

IRBs may incorporate the following structured evaluative questions aligned with al-ḍarūriyyāt al-khams:

(1) *Hifz al-Nafs* (Preservation of Life)

- Does the study address a genuine and significant health need?
- Are risks justified by necessity (*ḍarūrah*) and absence of safer alternatives?
- Does the research primarily serve therapeutic or public health benefit rather than commercial interest?

(2) *Hifz al-‘Aql* (Preservation of Intellect)

- Is informed consent demonstrably comprehensible to participants?
- Are safeguards in place to prevent therapeutic misconception?
- Are cognitively vulnerable populations adequately protected?

(3) *Hifz al-Māl* (Preservation of Wealth)

- Is participant compensation fair but non-coercive?
- Are sponsor–site contracts equitable and transparent?
- Are economically vulnerable participants protected from undue inducement?

(4) *Hifz al-Nasl* (Preservation of Lineage)

- Does the research involve reproductive, genetic, or heritable implications?
- Have long-term familial and societal consequences been considered?
- Is harm–benefit balancing applied to intergenerational impact?

(5) *Hifz al-Dīn* (Preservation of Religion)

- Are participants' religious obligations respected (worship times, modesty, dietary considerations)?
- Does the institutional setting provide space for spiritual accommodation?
- Could the protocol unintentionally compromise spiritual dignity?

(6) *Maṣlahah–Mafṣadah* Balancing

- Does the anticipated public benefit outweigh foreseeable harms?
- Are risks minimized to the lowest feasible threshold?
- Does the study align with national or communal health priorities?

Governance Implications

In practice, this model does not require separate Shariah approval structures. Rather, Maqāṣid-based reflection may be incorporated into existing IRB ethical deliberation forms as an additional evaluative column or checklist. This maintains regulatory harmonization while enhancing moral depth.

The integration model contributes to:

1. Strengthened ethical proportionality analysis
2. Increased public trust among Muslim participants
3. Institutional alignment with Shariah-compliant healthcare discourse
4. Preservation of international scientific credibility

By formalizing Maqāṣid reasoning within IRB deliberation, Malaysian hospitals can operationalize ethical pluralism without regulatory fragmentation.

DISCUSSION

This analysis indicates that Maqāṣid al-Sharī'ah provides an ethical framework that extends beyond procedural safeguards. While ICH-GCP prioritizes participant protection, scientific validity, and institutional accountability (ICH, 2025), Maqāṣid introduces purposive moral reasoning grounded in intention, public benefit, harm prevention, and long-term welfare (Rosman et al., 2019).

To illustrate the practical implications of Maqāṣid-informed governance, consider a hypothetical Phase I oncology trial conducted in a Malaysian public hospital. The trial evaluates a novel immunotherapy agent for advanced-stage cancer patients who have exhausted standard treatment options. The study offers modest financial compensation and access to an experimental intervention, but the probability of direct therapeutic benefit remains uncertain.

Under Western bioethical principlism, ethical acceptability would primarily depend on valid informed consent, proportional risk–benefit assessment, independent IRB approval, and compliance with GCP safeguards. Provided that participants are fully informed, risks are scientifically justified, and procedural standards are met, the study would generally be considered ethically permissible.

A Maqāṣid-based evaluation, however, would extend the analysis further. From the perspective of *ḥifẓ al-nafs* (preservation of life), the trial is ethically defensible if it aims to meaningfully advance life-saving knowledge and does not impose disproportionate harm relative to potential benefit. Yet Maqāṣid would also scrutinize whether desperation among terminal patients compromises genuine voluntariness, thereby implicating *ḥifẓ al-‘aql* (protection of rational agency) and raising concerns about therapeutic misconception.

From the standpoint of *ḥifẓ al-māl*, the compensation structure must not exploit socio-economically vulnerable participants, especially in public hospital settings where patients may perceive participation as a pathway to otherwise inaccessible care. Moreover, the principle of *maṣlahah* requires evaluating whether the anticipated societal benefit justifies exposing participants to early-phase risk, while *mafsadah* analysis demands careful consideration of long-term systemic implications, including public trust and institutional integrity.

While Western principlism may deem the trial ethically acceptable upon procedural compliance, Maqāṣid reasoning introduces additional layers of scrutiny: intention (*niyyah*) of sponsors and investigators, distributive justice, proportional necessity (*ḍarūrah*), and broader communal welfare. The integration of these considerations does not invalidate GCP standards but deepens ethical deliberation within Malaysia’s socio-religious context.

Several limitations of procedural principlism become more visible from a Maqāṣid lens. First, a strongly autonomy-centred framing can underemphasize communal impact and long-range societal effects, particularly in public hospitals serving vulnerable communities. Second, documentation-driven compliance may not sufficiently address intention (*niyyah*) or the ethical orientation of institutional culture; compliance does not automatically entail justice. Third, risk–benefit assessment is commonly expressed in biomedical metrics and statistical thresholds, leaving spiritual welfare and faith-informed perceptions of harm underexamined. These concerns do not negate Western bioethics but suggest areas where complementary reasoning can strengthen governance in plural contexts.

Maqāṣid does not introduce wholly foreign values. Its objectives overlap with Western principles: *ḥifẓ al-nafs* resonates with beneficence/non-maleficence; *ḥifẓ al-‘aql* aligns with autonomy; and *ḥifẓ al-māl* supports justice and protection against exploitation (Abdulahi Hashi, 2022). The key difference lies in foundation and orientation: Maqāṣid situates ethics within divine purpose and moral accountability, thereby adding teleological depth to procedural standards. From the perspective of purposive jurisprudence, Maqāṣid reasoning also brings to the foreground moral epistemology (the sources and aims of ethical knowledge), where accountability is not only institutional but also value-laden and oriented toward protecting human dignity and the public good (Ibn ‘Ashūr, 2006; Auda, 2008). This enriches ethical pluralism by showing that “compatibility” with global standards need not require the exclusion of faith-informed moral reasoning, especially in contexts where patients’ and communities’ ethical horizons include religious obligations and spiritual welfare (Sachedina, 2009).

In Malaysia, expanding discourse on Shariah-compliant healthcare governance suggests institutional readiness to embed Islamic ethics within broader governance structures (Mohd Noor & Mohd Noor, 2021). Extending this agenda to research oversight is therefore coherent with national socio-religious realities. At the same time,

international harmonization remains essential for scientific credibility and cross-border collaboration (ICH, 2025). Ethical integration must therefore preserve regulatory compatibility.

Read as ethical pluralism, the integration model allows universal procedural safeguards to coexist with culturally grounded moral reasoning. GCP provides governance architecture; Maqāsid supplies moral direction. Together, they support a comprehensive approach that preserves integrity while acknowledging spiritual, communal, and long-term welfare dimensions (Abdulah Hashi, 2019; Rosman et al., 2019).

The reviewed literature further indicates that Shariah compliance in Malaysian healthcare has evolved toward system-level framework building, with emphasis on governance, ethics, spiritual support, worship facilities, affordability, and access (Jamaludin et al., 2025). In medical tourism, Muslim-friendly and Shariah-compliant hospitals are framed as strategic advantages because they respond to patient expectations regarding worship accommodation and halal-certified care (Idrus et al., 2025). Shariah-derived models of medical interaction also underscore that clinical relationships and obligations are shaped by *fiqh mu'āmalāt* and Maqāsid considerations, linking ethics to contractual and institutional legitimacy (Taib et al., 2022).

Maqāsid-based Islamic bioethics has also developed as a structured framework that evaluates biomedical issues through intention, method, and end-goals, while weighing interest hierarchies, inclusivity, and degrees of certainty (Ibrahim et al., 2019). Malaysian fatwa practice similarly operationalizes *maṣlahah–mafsadah* balancing and prioritization (*tarjīh*) using the five essentials as evaluative criteria (Ibrahim & Harun, 2024). Internationally, scholars argue that Islamic jurisprudential principles can contribute to global bioethics by incorporating communitarian and family-centred values that may not be fully captured by liberal autonomy models (Muhsin et al., 2026). Empirical illustrations also show that Maqāsid principles can be institutionalized through policies that improve well-being, safety, and financial transparency (Azis et al., 2025), and can resolve ethical dilemmas by proportional balancing across Maqāsid levels (Ghalia et al., 2018).

The integration of Maqāsid al-Shariah into contemporary healthcare demonstrates a comprehensive ethical and operational framework that spans clinical care, hospital governance, community health, and preventive medicine. In end-of-life settings, palliative and hospice care grounded in Maqāsid principles emphasize holistic support—physical, psychosocial, and spiritual—while guiding ethically sound decisions such as withholding or withdrawing life-sustaining treatment in accordance with the preservation of life (*hifz al-nafs*) and human dignity (Azaman et al., 2021). At the institutional level, the development of patient-centred hospitals aligned with Maqāsid al-Shariah highlights the importance of preserving life, upholding justice, protecting dignity, and ensuring holistic well-being through hospital design, accessibility, and ethical governance (Ahmad Luqmanulhakim et al., 2023). Preventive healthcare innovations, including mobile health applications for early breast cancer detection, further illustrate how Maqāsid al-Shariah and *Qawa'id al-Fiqhiyyah* can guide digital health interventions toward health promotion and disease prevention (Badi'auzzaman, 2022), while chemoprevention strategies using natural products mentioned in Islamic sources reinforce the preventive dimension of safeguarding life and health (Azalan & Abdul Ghani, 2023). At the systemic and community levels, Shariah-compliant hospitals and sustainable community health models have been shown to strengthen healthcare delivery, align with Sustainable Development Goals, and operationalize the protection of life, intellect, faith, lineage, and wealth within modern health systems (Haque et al., 2025; Haque et al., 2024). From a bioethical perspective, the Maqāsid-based approach also supports transparent disclosure of diagnoses and prognoses to competent patients, particularly at the end of life, to protect their material and spiritual interests (Alfahmi, 2022). Moreover, analyses of healthcare service quality from a Shariah perspective demonstrate that embedding Islamic ethical elements within hospital management enhances patient satisfaction, institutional integrity, and overall service excellence (Rahman & Ahmad, 2020). Collectively, these studies indicate that Maqāsid al-Shariah provides not merely a theoretical moral framework but a practical and adaptable paradigm for advancing ethically grounded, patient-centred, and sustainable healthcare systems in Muslim contexts.

Taken together, Malaysia's evolving healthcare environment—marked by regulatory harmonization, medical tourism, and the institutionalization of Shariah-compliant governance—supports the view that contextualizing GCP within a Maqāsid framework offers an ethically responsive pathway. This approach does not weaken

scientific governance; it strengthens it by adding moral intentionality, communal accountability, and a holistic understanding of welfare.

Limitations Of The Study

This study is conceptual and normative and therefore does not include empirical analysis of IRB decision-making or trial implementation in Malaysian hospitals. Findings should be read as ethical proposals rather than institutional evaluations. Applicability may also vary across jurisdictions with differing legal and theological contexts. Future work could incorporate empirical methods—such as IRB interviews, policy analysis, or case studies—to test the feasibility and impact of Maqāṣid-informed governance.

CONCLUSION

Hospital-based clinical research remains crucial for therapeutic innovation and the development of safe and effective health interventions. Its legitimacy depends on scientific rigor and robust ethical foundations. International frameworks such as ICH E6(R3) and Malaysian GCP provide essential procedural safeguards for participant protection, risk proportionality, informed consent, and data integrity, and they remain indispensable for global harmonization and research credibility.

In Muslim-majority contexts such as Malaysia, this analysis suggests that Maqāṣid al-Sharī‘ah can serve as a complementary normative framework that strengthens ethical evaluation. The preservation of life, intellect, wealth, lineage, and religion, together with *maṣlahah* and harm prevention, offers a comprehensive moral structure that extends beyond compliance. Importantly, integrating Maqāṣid does not undermine international standards; it contextualizes and enriches them. While GCP provides operational governance, Maqāṣid adds teleological moral reasoning, spiritual accountability, intention, and communal welfare considerations.

Conceptually, this study contributes to ethical pluralism by showing how Islamic normative philosophy can engage constructively with contemporary bioethics without compromising scientific integrity. Practically, embedding Maqāṣid reasoning within Malaysian governance may enhance IRB deliberation, strengthen trust, and align research oversight with socio-religious realities.

In Malaysia’s evolving healthcare landscape, Maqāṣid-informed research governance represents a coherent ethical advancement. Scientific progress and faith-informed ethics need not be in tension; they can operate complementarily to safeguard dignity, promote justice, and support responsible innovation.

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