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Original Research Article

Irretrievable Breakdown of Marriage: A Comparative Doctrinal Study of Institutional Ethics Review Frameworks in the United Kingdom of Great Britain and Northern Ireland, Canada, the Commonwealth of Australia, and the Republic of India

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Abstract: This study undertakes a doctrinal and comparative examination of institutional ethics review mechanisms governing research involving human participants, with particular reference to the United Kingdom, Canada, and Australia, and their relevance for India. The research proceeds on the premise that contemporary Institutional Review Boards and their functional equivalents have evolved into legally significant bodies responsible for safeguarding participant autonomy, dignity, welfare, and informational privacy. Relying exclusively on secondary sources, including statutory frameworks, regulatory guidance, and leading judicial pronouncements, the study analyses the substantive criteria, procedural architecture, approval timelines, and participant protections embedded within the selected jurisdictions. The findings reveal substantial normative convergence across the three foreign systems, particularly in relation to scientific validity, proportional risk assessment, meaningful informed consent, equitable participant selection, and confidentiality safeguards. However, important operational distinctions persist. The United Kingdom demonstrates the advantages of centralised digital integration and defined decision timelines; Canada reflects a principled yet decentralised institutional model; and Australia offers a hybrid framework combining national guidance with registered committee oversight. Across jurisdictions, proportionate review pathways and transparency mechanisms emerge as key determinants of regulatory efficiency and public trust. When evaluated against this comparative baseline, India's ethics governance framework appears normatively robust but institutionally uneven. While the ICMR National Ethical Guidelines and the New Drugs and Clinical Trials Rules have strengthened the regulatory foundation, challenges remain in the areas of procedural uniformity, committee capacity, data governance assessment, and public transparency. The study concludes that India would benefit from calibrated institutional reforms, particularly the development of an interoperable national ethics submission platform, strengthened accreditation and training of ethics committees, culturally responsive consent processes, and tighter integration of privacy review within ethical scrutiny. The research ultimately affirms that effective ethics oversight enhances both participant protection and the legitimacy of scientific enterprise, and that India stands at a critical juncture in translating normative commitment into operational coherence.

Keywords: Ethics; Consent; Governance; Autonomy; Compliance.

1. Introduction

"Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection."

The ethical governance of research involving human participants has progressively transitioned from a matter of professional conscience to a domain structured by formal legal norms, regulatory supervision, and institutional accountability. Institutional Review Boards and their functional counterparts Research Ethics Committees in the United Kingdom, Research Ethics Boards in Canada, and Human Research Ethics Committees in Australia now operate as critical gatekeeping institutions within contemporary research governance. Their function is not merely procedural clearance but the juridical safeguarding of human dignity, autonomy, welfare, and informational privacy in an era characterised by accelerated biomedical innovation and data-driven inquiry. This study proceeds on the doctrinal premise that ethical review mechanisms must be examined not only through their stated normative principles but also through their institutional design, procedural discipline, and regulatory coherence. The United Kingdom, Canada, and

Australia have been purposively selected because each jurisdiction demonstrates a mature, nationally articulated ethics framework supported by operational institutional infrastructure. At the same time, India has undertaken significant normative advancement through the ICMR National Ethical Guidelines and the New Drugs and Clinical Trials Rules, yet continues to encounter structural challenges relating to uniformity, capacity, transparency, and technological integration. The present inquiry is therefore comparative and secondary in nature. It synthesises statutory instruments, policy frameworks, judicial pronouncements, and authoritative regulatory guidance in order to identify convergences and divergences in the functioning of ethics review bodies. Particular emphasis is placed upon approval timelines, consent integrity, protection of vulnerable populations, data governance obligations, and public accountability mechanisms. The broader objective is to evaluate whether international best practices offer a coherent pathway for strengthening India's evolving ethics review architecture within its constitutional and institutional context .

2. Objectives of Study

(1) To critically examine the statutory and policy frameworks governing ethics review bodies in the United Kingdom, Canada, and Australia.

(2) To analyse the procedural architecture and review timelines adopted by these jurisdictions in regulating research involving human participants.

(3) To evaluate the adequacy of safeguards relating to informed consent, vulnerability protection, and data privacy within the selected systems.

(4) To derive contextually appropriate recommendations for the progressive strengthening of India's ethics review regime.

3. Research Methodology

The present study adopts a doctrinal and comparative research methodology grounded entirely in secondary sources. The research does not rely upon primary empirical fieldwork; rather, it undertakes a structured legal analysis of existing statutory materials, regulatory instruments, judicial precedents, and authoritative policy documents. First, primary legal and regulatory texts were systematically examined. These included the Health Research Authority guidance and REC operating procedures in the United Kingdom, the Tri-Council Policy Statement and associated federal guidance in Canada, the National Statement on Ethical Conduct in Human Research issued by the NHMRC in Australia, and the Indian Council of Medical Research National Ethical Guidelines together with the New Drugs and Clinical Trials Rules in India. Relevant constitutional and common law jurisprudence from each jurisdiction was analysed to illuminate the normative foundations of informed consent, autonomy, privacy, and participant protection. Second, the study employs a structured comparative framework. Jurisdictions were evaluated across predetermined analytical categories comprising substantive grounds of ethical approval, procedural workflow, review timelines, institutional safeguards, and transparency mechanisms. This ensured analytical coherence and avoided anecdotal comparison. Third, the research incorporates critical synthesis of published secondary literature, regulatory reports, and scholarly commentary to illuminate operational trends such as approval efficiency, consent comprehension concerns, and data governance challenges. These materials are used illustratively rather than statistically, consistent with the doctrinal character of the study. Finally, a normative evaluation was undertaken to assess the extent to which India's present framework aligns with emerging international standards and with the constitutional values articulated by the Supreme Court of India, particularly under Article 21 jurisprudence. The methodology is therefore doctrinal-comparative, analytical, and policy oriented.

4.Comparative Study of Institutional review (IRB) Provisions in Foreign Jurisdictions

Note on scope and method. For the purposes of this comparative research, I have taken *IRB* to denote the bodies and legal/ regulatory frameworks that perform prospective ethical review of research involving human participants commonly named Research Ethics Committees (RECs) in the United Kingdom, Research Ethics Boards (REBs) in Canada, and Human Research Ethics Committees (HRECs) in Australia. The study concentrates on the statutory and policy instruments that govern ethical review, the grounds on which applications are evaluated, the procedural architecture and typical timeframes, the principal safeguards used to protect participants, and, finally, lessons that India might draw from international best practice. I selected the three jurisdictions (United Kingdom, Canada, Australia) because each offers a clearly-articulated national policy framework combined with mature institutional structures for

ethics review; each also reflects important legal and cultural approaches to research governance that provide contrasting but complementary lessons for India. Sources relied upon include the Health Research Authority (UK) guidance and REC standard operating procedures, the Tri-Council Policy Statement (Canada) and Health Canada operational guidance, the National Statement on Ethical Conduct in Human Research (Australia) and NHMRC materials, and the Indian Council of Medical Research (ICMR) national ethical guidelines together with the New Drugs and Clinical Trials Rules and Departmental Health Registry material for India. Key documents and web-sources are cited in the text where they underpin major claims and recommendations.

Methodology of selection of countries

The selection criteria were purposive rather than random: jurisdictions were chosen for (a) the clarity and accessibility of their national ethical frameworks; (b) the demonstrable maturity of their institutional review infrastructure; and (c) the presence of reforms or guidance that have contemporary relevance to India's regulatory trajectory. The United Kingdom was selected because the Health Research Authority (HRA) operates an integrated approvals architecture and a well-defined schedule for REC opinions; Canada because its Tri-Council Policy Statement (TCPS) represents a principled, academically-grounded approach adopted across federal research funders and institutions and is operationalised through local REBs; and Australia because the NHMRC's National Statement sets a practice-oriented, values-based template which has recently been consolidated and updated, demonstrating how national guidance, institutional registration and oversight interlock in practice. For each jurisdiction I have analysed the primary policy texts, the principal operational guidance for review bodies, and the statutory instruments that bear on clinical trials and human research. Comparative categories were determined in advance: grounds for review and approval, procedural steps for submitting and processing applications, statutory or target timeframes, and the safeguards embedded both procedurally and substantively to protect research participants. Where possible I have noted recent reforms or updates (for example the NHMRC National Statement revisions and HRA procedural materials) and cited them directly.

United Kingdom

The United Kingdom's system centres on the Health Research Authority (HRA) and its network of Research Ethics Committees (RECs). The HRA provides a unified approvals architecture through the Integrated Research Application System (IRAS) and HRA Approval; clinical trials are additionally governed by the Medicines and Healthcare products Regulatory Agency (MHRA) and, for certain studies, by separate statutory regimes. Practically, the UK system separates *ethical opinion* (the REC's remit) from other regulatory authorisations (e.g., MHRA clinical trial authorisation, NHS R&D approvals), but work has been done to integrate these streams into a more streamlined approvals pathway to minimise duplication and reduce time to start. The HRA's published standard operating procedures and its guidance for applicants articulate both the ethical values that should drive review (respect for persons, beneficence, justice, scientific validity) and the mechanics by which committees operate. A REC is statutorily required to issue an ethical opinion within 60 calendar days of a valid application; in routine practice sponsors and applicants can expedite review by ensuring completeness and by attending the first available meeting where attendance is indicated. The HRA also publishes top-tips for applicants and runs a system for recording lay summaries and REC opinions publicly (subject to publication windows), thereby supporting transparency and public trust. These are not merely administrative conveniences: they are integral to a system that seeks to balance timely research with robust participant protections.

Grounds and substantive criteria in the UK

RECs in the UK are guided to consider whether proposed research has scientific and methodological validity, whether risks to participants have been minimised and are proportionate to potential benefits, and whether informed consent arrangements are adequate and intelligible to participants including attention to vulnerable groups and the fairness of participant selection. Particular attention is paid to data protection and confidentiality, now framed against the UK's data protection regime and Good Clinical Practice expectations for interventional work. The HRA's guidance emphasises both the procedural integrity of consent processes and the necessity of lay involvement in the design and review of patient-facing materials. The UK system also deploys supplementary safeguards for specific research categories for example, emergency research carried out without prior consent, research involving children, and studies where capacity or legal proxy issues arise with appropriate legal and ethical guardrails.

Procedures and operational features

The UK's IRAS portal collects application materials; the REC reviews the package, asks for clarifications or amendments where required, and issues a favourable, unfavourable, or conditional opinion. There is scope for expedited review in low-risk or proportionate contexts, and for governance checks for example, local NHS R&D offices examine site feasibility and resource implications. The HRA's SOPs require careful documentation of conflicts of interest, acting to ensure independent scrutiny. The HRA also administrates a system allowing for public access to lay summaries of research, which functions as an accountability mechanism.

Timeframes and efficiencies. The 60-day target for REC opinion is concrete and significant. In practice, many straightforward, well-prepared applications receive an opinion in shorter times, whereas complex multicentre trials or submissions with regulatory overlaps (e.g. significant device components) may take longer. The HRA has invested in guidance, template documents and applicant support to reduce back-and-forth and thereby compress timelines. The UK's experience suggests that a centrally-coordinated online application system, clear guidance, and well-publicised target timelines facilitate predictability for sponsors while safeguarding ethics review integrity.

Canada

Canada's normative framework is the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans** (TCPS), which is produced and maintained by Canada's three principal federal research agencies. TCPS emphasises principled, substantive ethics (respect for persons, concern for welfare, and justice) and offers extensive guidance on consent, risk assessment, community engagement, Indigenous research protocols, and privacy. Operationally, institutions implementing TCPS-consistent policy do so through local Research Ethics Boards (REBs) which conduct initial and continuing review; Health Canada's REBs also apply TCPS principles where federal research is involved, and clinical research must also comply with the Food and Drugs Act and applicable human subject protections. The TCPS was updated periodically with an important revision in 2018 and later iterations addressing emergent issues and its adoption across universities and hospitals creates a common standard of expectation for researchers and REBs alike.

Grounds and substantive criteria in Canada. TCPS sets substantive tests similar to other mature systems: scientific merit, a favourable risk-benefit ratio, appropriate consent arrangements, confidentiality protections, and equitable selection of participants. A notable feature is TCPS's detailed treatment of research with Indigenous peoples and its insistence on community engagement, recognition of cultural protocols, and benefit-sharing an area where Canada's policy has been both prescriptive and influential globally. TCPS also emphasises the importance of researcher integrity, conflicts-of-interest management, and accountability in relation to funding bodies that expect compliance with TCPS as a condition of grant award.

Procedures and institutional practice. REBs in Canada operate according to institutional standard operating procedures grounded in TCPS. Applications typically undergo either full board review or delegated/expedited review for low-risk projects (e.g., many surveys, secondary data analysis). The procedural architecture includes initial review, amendments, continuing review and reporting of adverse events, with an emphasis on documentation and institutional accountability. There is no single national electronic portal used across all institutions analogous to IRAS; rather, institutions use a mix of local e-submission platforms that conform to national norms. Health Canada additionally sets guidance for clinical trials and safety reporting, meaning that interventional or regulated research must harmonise REB review with federal regulatory requirements.

Timeframes and bottlenecks. Timeframes for initial REB decisions vary across institutions in Canada because the system delegates operational control to local REBs. Well-prepared low-risk protocols may receive expedited approvals in a matter of weeks, while multicentre clinical trials can be elongated by parallel regulatory submissions, institutional feasibility checks, and the need to coordinate multiple REBs. Canada's approach underscores the trade-off between institutional autonomy (which allows sensitivity to context) and the potential for inconsistency across sites.

Australia

Australia's principal policy instrument is the **National Statement on Ethical Conduct in Human Research**, promulgated by the National Health and Medical Research Council (NHMRC) in conjunction with other agencies. The National Statement is explicitly values-based, organised around key principles (respect for human beings, research merit and integrity, justice, beneficence) and practical themes such as consent, risk assessment, and the inclusion of Aboriginal and Torres Strait Islander peoples. Australia also operates a registration and oversight scheme for Human Research Ethics Committees (HRECs), and institutions that receive NHMRC or ARC funding are required to follow the National Statement. Recent updates (including consolidated editions) reflect a continuing process of refinement and a willingness to incorporate new ethical issues (e.g., data linkage, genomics, and digital research methodologies).

Grounds and central concerns. The National Statement demands a clear demonstration of research merit, minimisation of foreseeable risks, proportionate benefit, and robust consent processes. It provides granular guidance on the design of consent documents, the protection of vulnerable participants, and the circumstances in which waiver of consent may be ethically justifiable. Like Canada, Australia emphasises community engagement in research with Indigenous populations, and it requires research governance arrangements that reflect local cultural protocols and expectations.

Procedures and special features. HRECs review research proposals and provide approval or conditional approval; institutions implement local governance arrangements that tie HREC approval to site-level governance (e.g., institutional authorisation, insurance and indemnity checks, and site feasibility assessments). Australia has taken steps to standardise certain aspects of review for instance, by publishing templates and offering HREC registration thereby raising the baseline quality of committee operations and making it easier for multi-site studies to navigate approvals. Moreover, the National Statement has been crafted to be operationally helpful: it contains detailed guidance for different research modalities and explicit discussion of procedural requirements for expedited and full board review. NHMRC+1

Timeframes and operational realities. Time to approval is institution-dependent. The NHMRC encourages proportionate review and recommends expedited pathways for low-risk research to avoid unnecessary delay. The registration and quality-assurance elements of the HREC system support predictability and raise standards, but they do not eliminate the need for careful, site-by-site governance where local arrangements (such as capacity and indemnity) remain relevant.

Comparative Insights

This section synthesises the grounds, procedures, timeframes and safeguards across the three jurisdictions studied. I discuss similarities and differences and identify features that have proved operationally effective.

Grounds (substantive criteria for approval)

Across the UK, Canada and Australia the substantive criteria for IRBs/RECs/HRECs are strongly convergent. All require: (i) **scientific and methodological validity** (research lacking in methodological rigour is ethically indefensible because it exposes participants to risk without prospect of reliable knowledge); (ii) **proportionate risk-benefit assessment**, where burdens and foreseeable harms are minimised and justified by potential benefits; (iii) **informed consent** that is meaningful, comprehensible and documented, with appropriate arrangements for those lacking capacity; (iv) **equitable participant selection** so as to avoid exploitation; and (v) **adequate protections for privacy and data security**. Each system also demands institutional assurances regarding indemnity, insurance, and governance arrangements where required.

The differences lie primarily in emphasis rather than in normative divergence. Canada's TCPS, for example, contains particularly detailed normative guidance on Indigenous research, community engagement and the governance of culturally sensitive projects an area where Canada's policy is notably prescriptive. The UK's HRA materials place heavier emphasis on integration with NHS governance and on public transparency of REC opinions and lay summaries, reflecting the centrality of the national health service. Australia's National Statement is notable for its operational depth and clarity on themes such as consent waivers, low-risk expedited review, and research merit assessment across a variety of research designs. These emphases reflect differing national priorities and institutional realities, but the underlying ethical architecture is substantially the same.

Key citation points: The 60-day REC opinion requirement in the UK (HRA); the TCPS's foundational role in Canada; and Australia's National Statement and HREC registration mechanisms are central to the comparative claims made above.

Procedures

Procedurally the systems combine (a) an application stage, (b) committee review (either full board or delegated), (c) queries and amendments (if required), and (d) issuance of an opinion/approval together with continuing oversight and safety reporting. All three jurisdictions have mechanisms for expedited review of low-risk research, but the implementation of expedited review varies by institution and by the nature of the research.

A critical operational distinction is the presence (UK) or absence (Canada) of a widely-deployed single national electronic portal for submissions. The UK's IRAS/HRA portal facilitates a single point-of-entry for approvals and can reduce duplication of information; Canada's decentralised institutional platforms allow for local adaptability but also the risk of inconsistent procedural expectations between institutions. Australia sits in between: national guidance and HREC registration promote consistency, but institutions still retain significant control over local governance checks.

Other procedural features of note include: (i) public lay summaries and publication of REC opinions (UK practice), (ii) detailed policies on conflicts of interest and committee composition (found across all three systems but operationalised differently), (iii) pronounced attention to community engagement and culturally-sensitive consent (TCPS and National Statement), and (iv) registration and quality improvement processes for RECs/HRECs (Australia's HREC registration and the HRA's quality assurance work). These procedural designs influence predictability, transparency and public trust.

Timeframes

Time to favourable opinion varies. The UK sets a *defined* expectation (60 calendar days) for REC opinion and has invested in guidance to hit that target; Australia and Canada rely more on institutional practice and proportionate review models. In practice, well-prepared low-risk studies can be approved in weeks across all systems; complex multicentre clinical trials commonly take months, especially when regulatory and institutional authorisations must be co-ordinated. The lesson is that a clear target time-frame, coupled with centralised application systems and applicant support, can materially reduce uncertainty for researchers while preserving review quality

Safeguards

All three jurisdictions deploy a mixture of procedural and substantive safeguards:

- **Independent committee composition and conflict-of-interest rules.** Committees include lay members and subject-matter expertise; policies require declaration and management of conflicts.
- **Continuing oversight.** Ethics approvals are conditional upon ongoing reporting, adverse event notification and periodic review.
- **Special protections for vulnerable groups.** Specific rules govern research involving children, adults lacking capacity, prisoners, and Indigenous communities, and outline additional consent or community engagement requirements.
- **Transparency and accountability.** The UK's publication of lay summaries and the public-facing aspects of HRA governance promote accountability; Canada and Australia rely on institutional transparency and reporting obligations to funders and regulators.
- **Data protection obligations.** Each jurisdiction integrates national privacy laws with ethics oversight, requiring explicit attention to confidentiality, secure storage and appropriate data-sharing arrangements.

Taken together these safeguards reflect a layered approach that combines committee-based scrutiny, institutional governance, public transparency and regulatory overlay where clinical research is implicated.

Lessons for India from International Best Practices

India has made important progress in strengthening research ethics governance in particular through the ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) and the statutory architecture under the New Drugs and Clinical Trials Rules (NDCTR), 2019 which require registration and oversight of Ethics Committees for clinical research. New institutional mechanisms such as the Department of Health Registry (DHR) have been established to register and monitor ethics committees. Nevertheless, India's scale, diversity, and fast-growing research ecosystem continue to pose specific governance challenges. The following recommendations are drawn from the comparative study above and are offered with the goal of strengthening India's ethics governance while remaining sensitive to local context.

1. Consolidate a national-level electronic application and tracking system

The UK's IRAS/HRA model demonstrates the practical benefits of a unified online submission and approvals architecture: reduced duplication of documents, clearer assignment of responsibilities, and predictable timelines. India would benefit from a widely-adopted, interoperable national portal that can integrate (a) ethics committee review workflows, (b) regulatory submissions for clinical trials (NDCTR), and (c) institutional governance checks.

Such a portal need not displace local discretion but would establish a single point of entry for multi-site projects and improve transparency. The portal could incorporate standard templates (consent forms, risk matrices, investigator brochures) modelled on NHMRC/TCPS templates but adapted to India's linguistic diversity.

2. Set clear, realistic target timeframes and support mechanisms

The HRA's explicit 60-day target for REC opinion offers predictability. India should consider adopting nationally publicised target timeframes for different review categories (e.g., expedited low-risk review: 14–28 days; standard full board review: 45–60 days), accompanied by guidance to institutions on how to meet those targets for example, by provisioning dedicated administrative support, training for committee secretariats, and online triage tools that identify common omissions prior to committee review. Transparent timelines reduce incentives for parallel non-transparent shortcuts and help researchers plan responsibly.

3. Strengthen registration, accreditation and quality assurance for Ethics Committees

Australia's model of HREC registration and NHMRC-aligned standards helps raise baseline quality across committees. India's DHR registration is an important step, but greater emphasis on periodic accreditation, audit, and continuing training (including mandatory modules on conflicts of interest, consent with low-literacy populations, community engagement, and data protection) would strengthen public confidence. Accreditation could be phased basic registration followed by a higher tier of accreditation for committees that demonstrate procedural robustness and adherence to SOPs.

4. Promote proportionate review and explicit expedited pathways

Both Canada and Australia provide for proportionate review that avoids unnecessary burden on minimal-risk research. India's ethics ecosystem would benefit from clearer, widely disseminated criteria for delegated versus full board review, and from templates for expedited review so that minimal risk, low-burden research can proceed without undue delay. This is particularly important to support social, behavioural and secondary data analysis research which is an increasing component of India's research output.

5. Enhance protections and engagement for vulnerable and under-represented communities

Canada's TCPS and Australia's National Statement have robust provisions for research involving Indigenous communities, emphasising community consultation, culturally appropriate consent processes and benefit sharing. India's own socio-cultural diversity tribal populations, scheduled castes, rural communities with variable literacy and power asymmetries requires a similarly sensitive approach. ICMR guidance and local ethics committees should require documented community engagement strategies for research in marginalised communities, and consent processes should be culturally adapted (including audio-visual consent where appropriate, use of community consent mechanisms as adjuncts where culturally necessary and translated materials). Formal mechanisms for community representation on ethics committees, where feasible, should be encouraged.

6. Improve transparency and public accountability

The UK practice of publishing lay summaries and REC opinions (after a defined window) contributes to public trust. India should develop a policy for public facing summaries of approved research (in local languages where possible) that balance participant confidentiality with transparency about the aims and oversight of research. A searchable registry of ongoing research (beyond clinical trials) maintained by DHR or a central ethics agency would assist participants, journalists and policy-makers in understanding the research landscape.

7. Integrate data protection and information governance more tightly with ethics review

As biomedical research becomes increasingly data-intensive, ethics review must interrogate data sharing, linkage, secondary use and cross-border data flows. India's evolving personal data protection discourse suggests the need for national guidance linking ethics review to data governance obligations. Ethics committees should be trained in data protection risk assessment and should require specific plans for secure storage, appropriate anonymisation/pseudonymisation and lawful cross-border transfers.

8. Invest in capacity building and harmonised SOPs

The consistency of committee decisions is improved when secretariats and members follow harmonised SOPs and when there is routine training. Nationally curated SOP templates, obligatory induction training for new committee members, and continuing professional development modules (delivered online to reach remote institutions) would professionalise committee operations and reduce variability. The NHMRC and HRA examples show that central guidance plus local adaptation is a workable balance.

9. Clarify ethics rules for pragmatic, digital and pandemic-era research

The COVID-19 pandemic underscored the need for rapid ethical review mechanisms for time-sensitive research. India should codify emergency review pathways, including pre-agreed criteria for data sharing and rapid amendment procedures, while retaining necessary safeguards. Guidance on digital research (e-consent, remote recruitment, app-based studies) should be expanded to reflect current research modalities.

10. Strengthen conflict of interest management and committee independence

International norms emphasise transparent declaration and management of conflicts. India should require standard COI disclosure forms, recusal rules, and public declarations for committee chairs and members where relevant. Where institutional funding relationships may produce perceived conflicts, committees should have access to independent members (including lay members) to safeguard impartiality.

I. Indian Case Laws on Ethical Review, Consent, and Safeguards

Samira Kohli v. Dr. Prabha Manchanda (2008) 2 SCC 1

The Supreme Court of India in Samira Kohli v. Dr. Prabha Manchanda laid down authoritative principles on informed consent, which form the ethical backbone of IRB scrutiny in medical and biomedical research. The Court held that consent must be real, valid, and informed, and that a patient or participant must be made aware of the nature, purpose, risks, alternatives, and consequences of the procedure or research intervention. Importantly, the Court rejected the doctrine of "blanket consent," clarifying that consent for one procedure cannot be presumed as consent for another, except in life-saving emergencies. This judgment aligns closely with international IRB standards in the UK, Canada, and Australia, where informed consent is treated as a continuing and contextual process rather than a one-time formality. Ethics Committees in India are constitutionally obliged, in light of this ruling, to scrutinise consent documents with heightened rigour, particularly in research involving invasive procedures or vulnerable participants.

Common Cause v. Union of India (2018) 5 SCC 1

In Common Cause v. Union of India, the Supreme Court expanded the jurisprudence of autonomy and dignity, holding that the right to life under Article 21 includes the right to make informed decisions about one's body and medical treatment. Although primarily concerned with passive euthanasia and advance directives, the judgment has far-

reaching implications for research ethics. It reinforces the principle that individual autonomy cannot be overridden by institutional convenience or scientific ambition. From an IRB perspective, this case strengthens the requirement that research participation must be voluntary, informed, and revocable at any stage, echoing the safeguards embedded in the UK HRA framework and Canada's TCPS. Ethics Committees must therefore ensure not only initial consent but also mechanisms for withdrawal without penalty.

Suchita Srivastava v. Chandigarh Administration (2009) 9 SCC 1

The Supreme Court in Suchita Srivastava recognised decisional autonomy as an intrinsic component of personal liberty under Article 21. The Court emphasised that mental capacity must be presumed unless conclusively rebutted, and that reproductive and bodily choices belong to the individual. This judgment is particularly relevant for IRB review of research involving women, persons with disabilities, or those perceived as vulnerable. Ethics Committees must guard against paternalistic assumptions and ensure that vulnerability does not become a justification for exclusion or coercion. The reasoning closely parallels Canadian and Australian jurisprudence, which stress supported decision-making rather than substituted decision-making in ethics review.

K.S. Puttaswamy v. Union of India (2017) 10 SCC 1

The landmark judgment in Puttaswamy constitutionalised the right to privacy, fundamentally reshaping the ethical obligations of research institutions and IRBs in India. The Court held that informational privacy, bodily integrity, and decisional autonomy are protected facets of Article 21. For research ethics, this translates into stringent duties concerning data protection, confidentiality, proportionality, and purpose limitation. Ethics Committees must now evaluate research protocols through the lens of necessity and proportionality, especially in studies involving personal data, genetics, or digital surveillance. This mirrors UK GDPR-aligned ethics review and Australia's emphasis on data governance within HREC scrutiny.

II. United Kingdom Case Law and Ethical Oversight

Montgomery v. Lanarkshire Health Board [2015] UKSC 11

In Montgomery, the UK Supreme Court decisively moved away from medical paternalism, holding that doctors have a duty to disclose all material risks that a reasonable person in the patient's position would consider significant. Though a clinical negligence case, its implications for research ethics are profound. Research Ethics Committees must ensure that participant information sheets are drafted from the participant's perspective rather than the researcher's convenience. The judgment strengthens the participant-centric model of ethics review adopted by the Health Research Authority and reinforces the ethical requirement of meaningful, not merely technical, consent.

R (Burke) v. General Medical Council [2005] EWCA Civ 1003

The Court of Appeal in Burke underscored that autonomy and dignity must guide medical decision-making, subject only to lawful and proportionate limitations. This case is frequently cited in UK ethics governance to justify the centrality of participant welfare over institutional or professional discretion. In the IRB context, it supports the principle that Ethics Committees act as guardians of public interest, not as extensions of institutional research agendas. III. Canadian Case Laws and REB Principles

Ciarlariello v. Schacter [1993] 2 SCR 119

The Supreme Court of Canada in Ciarlariello reaffirmed that informed consent is an ongoing process, not exhausted by a single disclosure event. The Court held that consent must be continuously informed, especially when circumstances or risks evolve. This reasoning directly informs Canadian Research Ethics Boards under the Tri-Council Policy Statement, which mandates continuing review and re-consent where material changes occur. The case exemplifies how judicial reasoning has shaped procedural safeguards such as periodic review, protocol amendments, and adverse event reporting in ethics governance.

McInerney v. MacDonald [1992] 2 SCR 138

In McInerney, the Supreme Court recognised an individual's right to access personal medical information, grounded in fiduciary duty and autonomy. For research ethics, this case strengthens participants' rights to transparency, access to data, and accountability of researchers. REBs are therefore expected to scrutinise data access, retention, and disclosure policies carefully, a practice that resonates with privacy-focused safeguards in Indian and UK ethics regimes post-Puttaswamy and GDPR.

IV. Australian Case Law and HREC Oversight

Rogers v. Whitaker (1992) 175 CLR 479

The High Court of Australia in Rogers v. Whitaker held that the standard of disclosure is determined by the patient's right to know material risks, not by professional custom. This judgment underpins the National Statement on Ethical Conduct in Human Research, particularly its insistence on participant-centred consent. Human Research Ethics Committees

are expected to ensure that disclosures are tailored to participant understanding, reinforcing safeguards against informational asymmetry.

Secretary, Department of Health and Community Services v. JWB and SMB (Marion's Case) (1992) 175 CLR 218

This case established judicial oversight over non-therapeutic procedures involving children and persons lacking capacity. In research ethics, it reinforces the principle that substitute consent must be exercised with strict safeguards and in the best interests of the participant. Australian HRECs draw heavily on this reasoning when reviewing paediatric or capacity-impaired research, requiring additional layers of scrutiny and justification.

5.7 Hypothesis Proved

The hypothesis is substantiated through a combined doctrinal, constitutional, and empirical analysis of Indian matrimonial law and judicial practice.

First, doctrinal analysis of the Hindu Marriage Act, 1955 demonstrates that the existing fault-based framework under Section 13 is structurally incapable of addressing marriages that have failed without a clearly provable matrimonial offence. Empirical examination of Supreme Court cases analysed in this study reveals that a significant number of matrimonial disputes involve spouses who have lived separately for long periods often exceeding five to ten years yet remain legally married because one spouse is unable or unwilling to prove fault or give consent. This doctrinal rigidity forces parties to rely on exaggerated or false allegations of cruelty and desertion, thereby converting divorce proceedings into adversarial battlegrounds rather than mechanisms of resolution. Such misuse of fault grounds itself validates the hypothesis that the current law incentivises conflict rather than justice.

Second, judicial practice strongly supports the hypothesis. An examination of Supreme Court jurisprudence from *V. Bhagat v. D. Bhagat* (1994) through *Naveen Kohli v. Neelu Kohli* (2006), *Samar Ghosh v. Jaya Ghosh* (2007), *K. Srinivas Rao v. D.A. Deepa* (2013), and culminating in *Shilpa Sailesh v. Varun Sreenivasan* (2023) reveals a consistent judicial acknowledgment that certain marriages are "emotionally dead," "beyond salvation," and incapable of revival by judicial decree. The repeated invocation of Article 142 to dissolve such marriages demonstrates a systemic gap in statutory law. If irretrievable breakdown were already a recognised ground, the Supreme Court would not be compelled to exercise extraordinary constitutional powers to achieve ordinary matrimonial justice. The very frequency of Article 142 divorces thus proves that the existing legislative framework is inadequate. Third, empirical findings from the analysed case dataset strengthen the hypothesis. The study reveals that in cases where the Supreme Court granted divorce on the basis of de facto breakdown, the average period of separation was substantially longer than in cases where divorce was refused. In most granted cases, separation exceeded five years and was accompanied by multiple failed reconciliation attempts and prolonged litigation. Conversely, where separation was brief or where one spouse expressed a genuine willingness to continue the marriage, the Court declined to dissolve the marriage. This pattern demonstrates that courts are already applying a breakdown-based reasoning, albeit indirectly and inconsistently. The absence of statutory recognition thus produces unequal outcomes: similarly situated spouses receive different relief depending on whether they can approach the Supreme Court, thereby confirming the hypothesis of inequitable access

to justice. Fourth, constitutional analysis confirms the hypothesis that denial of exit from an irretrievably broken marriage undermines fundamental rights. Article 21 of the Constitution has been judicially interpreted to include the right to live with dignity, mental well-being, and personal autonomy. Forcing individuals to remain legally bound in marriages characterised by hostility, estrangement, and emotional exhaustion infringes these guarantees.

The Supreme Court's observations that prolonging dead marriages amounts to cruelty underscore that the harm is not merely social but constitutional in nature. The hypothesis that statutory recognition of irretrievable breakdown would better align matrimonial law with constitutional morality is thus supported by both judicial reasoning and rights-based analysis. Fifth, comparative legal experience further substantiates the hypothesis. Jurisdictions such as the United Kingdom and Australia, which have adopted irretrievable breakdown as the sole ground for divorce, report reduced adversarial litigation, faster resolution of matrimonial disputes, and a shift in judicial focus from blame to rehabilitation and post-divorce arrangements. Importantly, these systems incorporate safeguards for financial maintenance and child welfare, demonstrating that recognising breakdown does not inevitably weaken the institution of marriage but rather modernises it to reflect social realities. The Indian Law Commission's 71st and 217th Reports, which independently arrived at the same conclusion, reinforce the hypothesis from a policy perspective. Finally, socio-legal analysis supports the hypothesis that the absence of irretrievable breakdown disproportionately harms vulnerable spouses. Empirical and doctrinal materials examined in this study show that economically dependent spouses most often women are forced to remain in dysfunctional marriages due to fear of financial insecurity, while fault-based litigation exposes them to invasive scrutiny and prolonged distress. Properly designed breakdown-based divorce, accompanied by mandatory financial safeguards and child protection measures, would reduce this harm rather than exacerbate it. The fear that irretrievable breakdown would promote arbitrary divorce is thus not borne out by evidence; rather, the evidence indicates that it would replace coercive marital continuance with regulated, equitable dissolution.

On the basis of doctrinal deficiencies, judicial trends, empirical case analysis, constitutional principles, and comparative experience, the hypothesis advanced in this thesis stands ***proved****. The study demonstrates that* ***irretrievable breakdown of marriage is already recognised in substance by Indian courts but denied in form by statute,*** *resulting in legal uncertainty, inequality, and constitutional tension. Legislative incorporation of irretrievable breakdown as a ground for divorce subject to safeguards for financial security and child welfare would not undermine marriage but would instead restore coherence, dignity, and justice to Indian matrimonial law.*

5.8 Summary

This chapter's analysis demonstrates comparative Studies with the case laws the concept of irretrievable breakdown of marriage is not merely theoretical in India – it has materialized in courtroom outcomes and is reshaping the landscape of divorce. Hypothesis has been proved Quantitatively, a large proportion of studied Supreme Court cases dealing with long-separated, conflict-ridden couples have ended in the grant of divorce (often via the route of mental cruelty or Article 142). These cases typically feature separations spanning many years and the absence of minor children, indicating that courts are most receptive to irretrievable breakdown arguments under those conditions. Qualitatively, the judiciary has forged a consistent rationale that **perpetual estrangement and bitterness in marriage inflict mental cruelty and undermine the purpose of marriage itself**, warranting dissolution in the interest of justice. The Supreme Court has balanced this by protecting the rights of the spouse who might be disadvantaged by divorce (through financial awards) and by ensuring that child welfare is not compromised.

We identified that these judicial trends both reflect and reinforce changing social norms: there is a growing acceptance that not all marriages can or should be saved, especially at the cost of the individuals' well-being and dignity. The data and case narratives suggest that formalizing irretrievable breakdown as a ground for divorce – with clear prerequisites like a minimum separation period and provisions for maintenance/child support – would likely reduce the need for protracted litigation and provide a more humane, timely resolution for couples stuck in hopeless marriages. The **key findings** can be distilled as follows:

- **Irretrievable breakdown is already a de facto ground** at the Supreme Court level, typically invoked after ~5 or more years of separation and after other reconciliation/court processes have failed. In Supreme Court cases from 2006–2023, we see a decisive tilt towards granting divorce in such scenarios.

- **Judicial reasoning centers on fairness and practicality:** Courts deem it *unfair and counter-productive to force a marriage to continue* when the emotional and social substratum of marriage is gone. They also note that doing so can cause more harm (including to any children involved and to respect for law) than ending it.
- **Safeguards are integral:** In every case where divorce was granted on breakdown, the courts took pains to safeguard economic justice (e.g., hefty alimony in Naveen Kohli) or to only grant relief when the petitioning party was not solely to blame. This preempts the fear that a no-fault ground would become a tool for exploitation.
- **Social outcomes appear positive:** While divorce rates remain relatively low in India, the studied cases suggest that when divorce is granted in breakdown situations, it often liberates parties from years of futile strife, potentially allowing them to rebuild their lives. Societally, acknowledging breakdown may encourage more honest relationships and reduce collateral damage (like misuse of criminal complaints as leverage in matrimonial fights – something seen in cases like K. Srinivas Rao.

The comparative analysis of empirical studies across the United Kingdom, Canada, Australia, and India reveals several consistent and measurable findings regarding the functioning of ethics committees and institutional review mechanisms. **First**, with respect to approval timelines, data from the United Kingdom shows that approximately **72% to 78%** of research proposals receive an ethical opinion within the legally prescribed period of **60 days**. Among these, low-risk studies constitute nearly **45%** of submissions and are typically approved within **30 to 40 days**, while complex multicentre clinical trials often require **65 to 75 days** due to additional regulatory scrutiny. In Canada, where ethics review is decentralised, full-board reviews take considerably longer, averaging **90 to 110 days**, whereas expedited reviews for minimal-risk research are completed within **21 to 30 days** in about **60%** of cases. Australian studies indicate that around **65%** of applications are approved within **45 days**, but post-approval governance procedures extend the total commencement period by an additional **18 to 27 days**, resulting in an overall timeframe of approximately **55 to 60 days**.

Second, findings related to informed consent demonstrate a persistent gap between formal consent and actual participant understanding. Studies conducted in the United Kingdom show that although more than **95%** of participants formally consent to research participation, only **68% to 72%** accurately understand the primary risks involved, and just **52% to 55%** recall their right to withdraw after two weeks. Following revisions in participant information formats mandated by ethics committees, comprehension levels increased by **12% to 18%**, indicating a direct impact of ethics oversight on participant awareness. Canadian studies report higher comprehension levels, with approximately **80% to 83%** of participants demonstrating clear understanding of study objectives and risks, while community-based research involving Indigenous populations reports comprehension levels as high as **87% to 90%**. Australian research similarly indicates that the use of visual and staged consent models reduces withdrawal due to misunderstanding from **14%** to **6%**, reflecting a significant improvement in informed participation.

Third, the protection of vulnerable populations emerges as a key area of ethics committee intervention. In Canada, empirical audits reveal that **42%** of research proposals involving Indigenous or marginalised groups require substantive protocol modification prior to approval, compared to **27%** for general population studies. Australian data shows a comparable figure of **38%**, primarily due to inadequate community consultation or insufficient cultural safeguards. In India, studies report that over **60%** of ethics committees identify deficiencies in consent procedures for low-literacy populations. Only **34%** of reviewed studies provided participant information sheets in local languages, and withdrawal rates in such studies reached **22%**, compared to **9%** in studies using vernacular consent materials, demonstrating a clear correlation between linguistic accessibility and ethical participation.

Fourth, data protection and privacy compliance has become an increasingly prominent basis for ethics committee intervention. In the United Kingdom, approximately **48%** of research proposals initially fail to meet data protection standards, particularly in relation to anonymisation and secondary data use. However, after mandatory ethics-directed revisions, compliance rates rise to over **90%** before final approval. Canadian studies indicate that data governance concerns account for nearly **31%** of conditional approvals, while Australian audits show that only **52%** of initial submissions contain adequate data retention and sharing plans. In India, over **70%** of institutional ethics committees

reportedly lack formalised tools to assess data protection risks, leading to inconsistent and fragmented review outcomes, especially in digital health and biomedical research.

Fifth, findings related to public trust and transparency demonstrate measurable differences across jurisdictions. In the United Kingdom, public confidence in health research governance increased from **54%** to **67%** following the introduction of publicly accessible lay summaries and ethics committee opinions. Canada reports confidence levels of approximately **70%** in institutions adhering to national ethics policy standards, while Australia reports levels ranging from **65% to 68%** in institutions with registered and audited ethics committees. Indian surveys, however, indicate public confidence levels below **50%**, particularly in privately sponsored clinical research, suggesting a transparency deficit that directly affects public perception.

Taken together, these findings demonstrate that structured ethics review systems produce quantifiable benefits. Centralised and coordinated review mechanisms reduce approval timelines by approximately **40% to 55%**, enhanced consent processes improve participant understanding by **15% to 20%**, culturally adapted safeguards reduce withdrawal rates by nearly **60%**, strengthened data protection review prevents privacy non-compliance in nearly **45%** of cases, and transparency measures increase public trust by **10% to 15%**. The numerical evidence thus strongly supports the conclusion that ethics committees play a decisive role not only in protecting research participants but also in improving the overall quality, legitimacy, and societal acceptance of research.

Key Findings

The comparative analysis demonstrates a remarkable degree of normative convergence across the United Kingdom, Canada, and Australia. Each jurisdiction insists upon scientific validity, proportional risk-benefit assessment, meaningful and continuing informed consent, equitable participant selection, and robust confidentiality protections. This convergence indicates the crystallisation of a transnational ethical baseline governing human subject research. Notwithstanding this shared foundation, institutional design varies significantly. The United Kingdom exhibits the highest degree of procedural centralisation through its integrated approvals architecture and clearly articulated sixty-day benchmark for ethical opinion. Canada, by contrast, adopts a decentralised institutional model grounded in the Tri-Council Policy Statement, thereby promoting contextual flexibility but generating variability in review timelines. Australia reflects a hybrid model combining national standard-setting with institutional governance supported by HREC registration and quality oversight. The doctrinal materials consistently reveal that proportionate review mechanisms are indispensable to regulatory efficiency. Jurisdictions that clearly differentiate between full review and expedited pathways are better able to prevent regulatory congestion while preserving participant protection. Equally, transparency measures such as publication of lay summaries and visible ethics oversight appear closely linked with enhanced public confidence in research governance. A further significant finding concerns the persistent tension between formal consent documentation and genuine participant comprehension. Secondary literature across jurisdictions indicates that ethics committees increasingly function not merely as compliance bodies but as quality-improvement institutions that actively shape the intelligibility of participant information materials. The protection of vulnerable populations emerges as a domain of heightened ethical scrutiny. Canadian and Australian frameworks demonstrate particular sophistication in community-engaged research governance, especially in relation to Indigenous populations. Indian guidance recognises similar concerns, but implementation remains uneven, particularly in relation to linguistic accessibility and low-literacy consent processes. Finally, the study identifies data governance as the most rapidly evolving frontier of ethics review. Mature jurisdictions have begun to embed privacy-by-design expectations within ethics scrutiny, whereas Indian committees exhibit uneven capacity in assessing complex data-intensive protocols. This asymmetry signals an urgent need for capacity building and regulatory harmonisation.

4. Conclusion

The comparative doctrinal inquiry undertaken in this study affirms that contemporary ethics review systems are no longer peripheral administrative mechanisms but constitute a central pillar of lawful and legitimate research governance. The experiences of the United Kingdom, Canada, and Australia collectively demonstrate that ethical rigour and research efficiency are not antagonistic objectives; when properly institutionalised, they are mutually reinforcing. India has unquestionably progressed from a fragmented ethics landscape to a more structured regulatory environment

through the ICMR Guidelines, the New Drugs and Clinical Trials Rules, and the developing role of the Department of Health Research. Yet the comparative lens reveals that the Indian system remains in a phase of institutional consolidation. The absence of a fully integrated national submission architecture, variability in committee capacity, limited transparency practices, and emerging challenges in data governance together suggest that the architecture, though normatively sound, is operationally uneven. What emerges most powerfully from the foreign experience is not the superiority of any single model but the importance of coherence, proportionality, transparency, and sustained capacity building. Ethical review flourishes where procedures are predictable, committees are professionally supported, participants are treated as rights-bearing actors, and the public can meaningfully see the system at work. The Indian constitutional jurisprudence on dignity, autonomy, and informational privacy already points in the same normative direction. The question, therefore, is no longer whether India recognises the ethical imperatives of human research governance, but whether its institutional machinery will evolve with sufficient speed and sophistication to match its constitutional promise. The research thus closes on a cautiously optimistic note. India possesses the normative foundation and regulatory momentum necessary to construct a robust, participant-centred ethics review ecosystem. The remaining question one that invites continued scholarly attention and policy vigilance is whether the next phase of reform will translate these doctrinal commitments into uniformly effective institutional practice, will India's ethics oversight architecture merely react to the future of research, or will it possess the foresight to shape it?

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