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Standardizing Institutional Research Ethics in Medical Education Across India

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Abstract

India's vast population has positioned the country as a major hub for clinical research, drawing considerable global pharmaceutical interest. While the Indian Council of Medical Research guidelines and the New Drugs and Clinical Trials Rules 2019, provide a robust national framework for ethical conduct, their implementation across medical institutions remains inconsistent. This variability is reflected in the functioning of Institutional Ethics Committees (IECs) across various medical institutions in India especially during the period of 2018-2025. In-order to address the lackadaisical performance of the institute ethics Committees, a common ethical governance framework should be created, which could lead to transparency, accountability, and expertise with the use of artificial intelligence and machine learning. However, full utilization of IECs should be enabled, with the goal being to make ethical practice uniform across emerging and already established medical institutions in India, and setting a standard in this respect globally.

Keywords: Clinical Research India, Institutional Ethics Committees (IECs), Research Ethics, ICMR Guidelines, Ethical Governance Framework, Artificial Intelligence.

Introduction

India, with its current population of over 1.46 billion, has a significant burden of health-related disorders that imposes an urgent need to expand the clinical research domain addressing the various healthcare challenges. In the past, the country has undergone a notable change in the clinical research landscape [1]. With the current resource of a large pool of skilled professionals, enormous patient load, and the genetic and cultural diversity, India remains the primary focus of global pharmaceutical companies for clinical studies [2]. This has contributed to a sharp rise in advanced clinical studies that lead to a drastic shift in evidence-based medicine. Clinical research is a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health [3]. To protect the privacy of the participants in the study and to maintain the confidentiality of the procedure and records, an ethical committee approval with a written informed consent forms the basis for ensuring the integrity of scientific research [4]. However, implementation of the existing national guidelines on ethics and legal provision over the newly arising medical institutions in India is still a large challenge.

These institutions moreover highlighted the growing gap in the ethics framework and ethical review committee across the medical institutions, clearly stating the urgent need towards a common ethical framework that every institution must adopt to promote an atmosphere of ethical accountability within the clinical research ecosystem.

Research Ethics: International and Indian Perspectives

Globally, the first instances of recognition of ethical constraints on human research date back several decades. The Declaration of Helsinki, revised in 1975 during the 29th General Assembly of the World Medical Association at Tokyo, emphasized that all studies involving human participants should be defined in a research protocol and submitted for independent ethics committee review [5]. In their turn, the Belmont Report (1974) laid empha-

sis on the need for a comprehensive ethical review for all clinical research involving human subjects, thus advocating respect for persons, beneficence and justice [6].

Large ethical syntheses from around the world have, over time, produced a common framework of accountability in the conduct of biomedical research [7]. Such a common framework in India traces its roots to the ICMR Policy Statement of 1980, which, for the first time ever, outlined basic ethical safeguards and defined the minimum requirements for Ethics Committees. The document marked the beginning of formalized ethical review in this country [4]. Building on this, the ICMR Ethical Guidelines for Biomedical Research on Human Subjects were released in 2000 and modified further in 2006. the guidelines extended the scope of ethical governance to cover biomedical research and epidemiological studies and public health research through specific operational directives for researchers and institutions. The GCP guidelines entered into effect in India during 2001 to create a structured system for evaluating clinical trials through ethical and scientific and regulatory standards [8].

Further streamlining of ethical governance was carried out by the Mo HFW in 2002 with the publication of definitions and operational expectations of ECs, recognizing the necessity for independent ECs by researchers who are not institutionally anchored [9]. A major milestone was reached in 2007 when the Clinical Trials Registry–India (CTRI) was set up by the ICMR's National Institute of Medical Statistics [1]. The registry required all clinical trials to register publicly which created an environment of open research practices that built trust with the public while maintaining accountability in clinical trials. The established milestones demonstrate how India has progressively built ethical review systems to fulfill international standards and improve its biomedical research oversight. Medical institutions follow these policies yet their actual compliance requires thorough evaluation through systematic assessment.

Variability in Institutional Research Ethics Standards Across Indian Medical Colleges

Lack of standardized bioethics training may be one of the major contributing factors for inconsistent application of research ethics practices within Indian medical institutions. Bioethics is taught in the curricula for undergraduate or postgraduate medical courses in most Indian institutions. However, adequate training in the core ethical principles and procedures that are intended to protect human beings as subjects in such research is normally not imparted to members of the Institutional Ethics Committees as well as to the investigators. Ethical reviews have often become mere procedural formalities devoid of rigorous evaluation. The IEC approval, though mandatory, is often considered the least one could do and satisfying it does not guarantee any ethical merits in the conduct of research [10]. The onus rests primarily on the individual investigator's awareness and commitment to uphold the ethical standards which vary considerably among institutions.

Evidence from many institutions indicates that Ethics Committees function sporadically, meeting irregularly, with irregular review and decision-making processes [11]. In many environments, ethical review remains superficial, generally confined to the review of consent forms and the evaluation of scientific merit. Critical areas to be reviewed include risk–benefit analysis, participant compensation, the inclusion of vulnerable subjects, the management of conflict of interest, and post-trial care. The blindness to these issues is holding back as them ethics committee from achieving one of its primary goals, protecting research participants while also providing scientific and social justification for the research. The concern is that India wants to be a global centre for clinical research and does not have a system in place to maximize the value of research through governance, resources, support, training, and to minimize the risk of ethical violations/wrongs associated with research. in addition, because of the emergence of novel research areas like biobanking, biorepositories, digital health technology, and big data, there are significant challenges of regulation that need careful and thoughtful development.

To facilitate the full value of these areas of research, a comprehensive national model for institutional ethics committees is necessary. the model must provide regular training and education for research agendas for faculty, students, and committee members, provide periodic audits, and promote continuing ethics education. the development of a strong and comprehensive state-wide model will enable ethics committees to operate effectively and to facilitate significant value through ethical review mechanisms by adhering to global best practices and through participant-centered structures.

Table1: Comparison of the Different Criteria Across the Current Global and Ethical Standards

Sl. No	Criteria Compared	Global Standards	Indian Equivalent	Identified Gaps / Lacunae	Recommendations
1	Ethical Principles	World Medical Association (WMA) – Declaration of Helsinki	Indian Council of Medical Research (ICMR) Ethical Guidelines	Lack of adherence to core ethical principles	Single unanimous ethical framework considering the cultural background
2	Functioning of Ethics Committees	Continuous monitoring	Inconsistent follow-up across institutions	Limited post-approval monitoring	periodic audits and meeting minutes submission
3	Protection of Vulnerable Populations	Strong emphasis on justice, autonomy, and protection	Framework still evolving	Weak or inconsistent enforcement	Strengthen guidelines and enforcement for vulnerable groups

4	Data Privacy & Confidentiality	Strict confidentiality and data protection norms	Unstable and variable systems	Minimal enforcement of data protection	Ensure mandatory compliance with regional data privacy standards
5	Research with Complementary / Traditional Medicine	Expanding structured guidance globally	Emerging ethical framework	Lack of structured framework	Develop ethics guidelines incorporating Ayurveda and AYUSH
6	Training & Capacity Building	Mandatory training with refresher courses	Basic bioethics training	Limited scope and outdated content	Introduce compulsory bioethics and research integrity modules
7	Legal and Regulatory Issues	Strong legislation with robust enforcement	Fragmented laws and enforcement challenges	Overlaps and gaps in legal provisions	Formulate a comprehensive National Research Ethics Law
8	Publication & Transparency	Transparent reporting and mandatory disclosures	Limited transparency	Inadequate protocol reporting	Mandate registration and publication of all research protocols

The Challenges in Research Ethics Enactment in Burgeoning Medical Institutions of India

In India, most of the upcoming medical institutions have systematic and structural barriers in creating and maintaining an effective ethical oversight for research. In a recent evaluation of ethical committee across eleven institutions, these deficiencies were laid bare. There was clearly a gap in the understanding of the national ethical framework and the working practices that support enhancing the well-being of research participants. The findings revealed widespread gaps regarding knowledge of Schedule Y, some members were not sufficiently familiar with GCP, and many failed to identify the important documentation for ethics review. Alarmingly, some committees appeared not to grasp the ethical implications and regulatory ramifications of IEC approval itself [12]. One-third of the committees reported having developed SOPs and conducted internal audits assessing their operations, though these practices were applied rather sporadically. Some improvements were noted over ICMR-WHO surveys conducted in 2003 and 2007; however, the overall impression reflects the still-surviving structural limitations and lack of harmonization.

A separate 2009 study of the composition and roles of IEC members in Pune had comparable findings. Although most members of such committees are well-established, recognized professionals with impressive academic and research credentials, only about 50% of these hold sound knowledge on the basic ethical principles involved. The fact that there is a mismatch with regard to the seniority of the members and by which standards they understood ethics in guidance was completely disheartening in this context because it was observed in newly formed medical institutes, where no form of training was instituted to enable the differentiation of committee roles on the bases of experience rather than ranking [4]. A recent audit on the compliance of IEC approval letters with Schedule Y and ICMR guidelines has intensified the issue. The probe managed to identify various loops in regulations such as absence of a lawyer and social scientists in committee meetings, quorum discrepancies, as well as scrutiny into very critical documents like clinical trial agreements and insurance policies [13]. These ones showed that, most of the time, the ethical review was superficial, leaving out essential issues such as participant protection and trial governance. All of these findings point out the fact that inadequate formal training, meagre institutional support, and the absence of procedural rigor prevent the effective implementation of research ethics in the budding medical institutes of India. Without proper targeted interventions such as structured capacity-building, standardization of review mechanisms, and vigorous regulatory oversight- these emerging institutions may fail to comply with national and international standards for ethical research.

Guidelines in Ethics at Global and National Level

Guidelines in Ethics are meant to promote safe, respectful, and responsible human research. The Declaration of Helsinki includes requirements for informed consent, protection of participants, risk-benefit analysis, and the overseeing of independent ethics committees. CIOMS-WHO sets out certain complementary guidelines that highlight vulnerable groups of people, community engagement, and equitable benefits in low- and middle-income countries [14, 15]. International Council for Harmonisation – Good Clinical Practice (ICH-GCP) guidelines offer international standards for clinical trial design, conduct, and reporting to protect participant welfare and data integrity [16]. United Nations Educational, Scientific and Cultural Organization's (UNESCO) Universal Declaration on Bioethics and Human Rights promotes ethical cooperation and capacity building worldwide, whereas the Belmont Report established principles of respect for persons, beneficence and justice that remain central to research governance [17, 4].

In India, the Indian Council of Medical Research (ICMR), Central Drugs Standard Control Organization (CDSCO) and Clinical Trials Registry–India (CTRI) collectively shapes the ethical landscape [18,19]. The ICMR's 2017 National Ethical Guidelines, most recently expanded in March 2025 with integrative medicine provisions lay out standards for clinical, genomic, AYUSH, and public health research, including mandates for informed consent and inclusion of AYUSH experts in traditional medicine trials [18]. Under the New Drugs and Clinical Trials Rules (NDCT) 2019, all Institutional Ethics Committees (IECs) must register with the CDSCO and renew their registrations every three years. However, recent data show that only approximately half of the IECs are registered, and far fewer comply with the reregistration requirements [20].

Core Ethical Competencies in Medical Research

The National Medical Commission (NMC), instituted in 2020, regulates medical education and clinical ethics in India; howev-

er, its accreditation criteria do not mandate active research ethics infrastructure, such as functioning IECs or strict adherence to GCP [21-23]. Although postgraduate theses involving human participants require IEC approval as per the ICMR, the absence of mandatory IEC presence in postgraduate program accreditation creates a policy gap Except for the regulatory frameworks which compel IRB oversight, protections of vulnerable populations and informed consent under FDA guidance, the US has provisions in the Common Rule (45 CFR 46). The models range from the ethics that the United Kingdom, through the General Medical Council (GMC), and Australia, through the Australian Medical Council (AMC), incorporated deeply into educational as well as research standards. All these models have universal ethical principles — autonomy, informed consent, beneficence, non-maleficence, and justice — behind guiding both teaching and practice [24-26].

Faculty members, as well as the administrative part, thus are custodians of these ethical practices among medical institutions beyond the required regulatory authorities and that would imply that they would be the source of motivation for how such Institutional Ethics Committees (IECs) are made fully aware, at least reasonably resourced, and constantly held accountable. The ICMR and FERCI have to play national proactive leadership to guide the development and commencement of structured training programs for IEC members. Clinical trial sponsors are key stakeholders in the entire research process and ought to own up this within their scope to being part of such capacity-building initiatives.

It is imperative that ethical training should be a comprehensive education to help IEC members fully understand the realities of clinical research as it pertains to the protection of vulnerable populations by preventing therapeutic misconception, improving informed consent and clarifying subject compensation and insurance [27]. As non-scientific members will often be included within the IEC, all training must be tailored to allow all participants, regardless of their educational background, the ability to perform their respective roles effectively. It is the responsibility of academic leaders and administrators to ensure that bioethics is incorporated into the curricula of academic institutions in order to in-still an early awareness and ethical responsibility in future researchers.

Integrating Research Ethics into the Medical Curriculum

Over the past few decades, there has been fortifying recognition of the effective incorporation of ethics education in medical training. Most such endeavours have in fact oriented focusing professional ethics and clinical conduct, neglecting the notion of ethics as applied to research involving human participants. Though medical ethics have been integrated into foundation courses of undergraduate curricula, research ethics are among the few and mostly unattended areas in many Indian medical institutions.

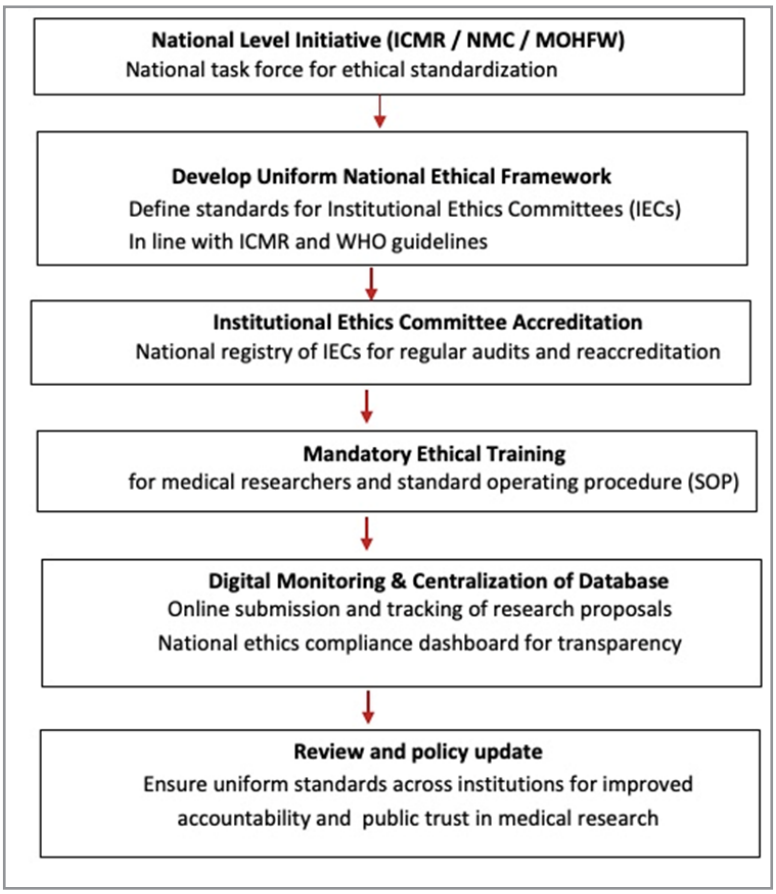

Figure 1: Model of the Work flow to be Integrated in the Indian Medical Research

Assessment and Accountability Mechanisms

A national legal mandate is essential to create a cohesive ethical ecosystem across new medical colleges in India. This should codify the ICMR guidelines using NDCT and NMC oversight, enforce IEC registration via the Department of Health Research (under the Ministry of Health and Family Welfare, Government of India), Central Drugs Standard Control Organization, and require fixed-term accreditation, backed by regular audits.

Importantly, community participation through the inclusion of lay members in IECs, public trial registration via CTRI, adverse event reporting, and ongoing guideline updates must be embedded. This framework ensures consistency in governance and risk oversight, fortifies participant protection and fosters public trust in biomedical research [30].

Recommendations for Reform

A coordinated task force under the mentorship of the apex institute should be established. Key strategies may include the development of digitalized questionnaires (such as Google Forms), by sharing its SOPs, submission forms, committee charters, and adverse event protocols, and hosting governance workshops and peer audits, which might significantly strengthen the ethical framework in peripheral medical colleges. Additionally, the mandatory implementation of an ethical performance feedback system can guide institutional actions, foster accountability at both individual and institutional levels, and enhance the responsiveness of IECs. Such measures will not only strengthen ethical governance but also improve institutional preparedness for the National Institutional Ranking Framework (NIRF), National Assessment and Accreditation Council (NAAC), and National Accreditation Board for Hospitals & Healthcare Providers (NABH) accreditation, ultimately ensuring a harmonized and well-structured ethical standard across emerging medical institutions.

Use Artificial Intelligence in Standardizing Institutional Ethics

Artificial intelligence and machine learning could be incorporated across various central institutes for guideline integration, proposal screening, checklist and scoring system for ethical review, maintaining consistency across various institutes, to educate and train the students and staff of various central institutes, monitoring and follow up of the documents thereby maintaining a transparency in the process and setting the standards of global bench marketing.

Conclusion

Ethics must form the backbone of medical education in India, establishing a unified moral compass that imbues future doctors with the values of trust, compassion, and integrity. Ethical principles are non-negotiable as per the World Medical Association, and must be consistently integrated into training and research. India's Competency-Based Medical Education (CBME) framework, with its Attitude, Ethics and Communication (AETCOM) module (2019, revised 2024), provides an entry point for integrating ethics into MBBS curricula nationwide. Only through a cohesive, enforceable ethical foundation embedded in governance, training, transparency, and accountability, India's medical community will be able to meet the evolving healthcare challenges, preserve the sanctity of the doctor–patient relationship, and honour the nobility of the medical profession.

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