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The Function, Role, and Challenge of Institutional Review Boards (IRBs) in Maintaining Research Ethics in Indian Universities

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ABSTRACT

Institutional Review Boards (IRBs), also called Ethics Committees in India, are institutional regulatory bodies formally established in academic and research institutions to ensure compliance with accepted ethical standards for all research involving human participants. These committees are responsible for scrutinizing research proposals to evaluate the harm and benefits of studies, validate the sufficiency of informed consent, and safeguard the rights and welfare of research subjects. This paper gives a comprehensive analysis of the role, framework, efficacy, and problems encountered by IRBs at Indian universities. Further, the paper seeks to explore imperative role of ethical stewardship in university research through analysing regulatory models, university practice, and actual case studies. The paper points towards the immediate necessity of capacity development, standardization, and policy overhaul to enhance ethical oversight in Indian academia.

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I. INTRODUCTION

With academic research advancing along various fields, from biomedicine to sociology and education; the need to carry out ethnically healthy investigations has never been so paramount. Human research is inherently risky to cause harm, exploitation, or violation of rights, and therefore requires institutional oversight and containment of these risks. This mandate has been placed on Institutional Review Boards (IRBs), or Ethics Committees, to review research protocols for ethical acceptability. These bodies have become especially significant in the Indian academic context, where research output is expanding, and diverse populations are increasingly being engaged as study participants.

In India, ethical review is an emerging concern not just for medical and pharma research but also for social sciences, education, psychology, and e-research streams. Although some institutions have well-established IRBs, others are struggling with procedural inefficiencies, non-awareness, and poor training. This paper intends to discover the way IRBs in Indian universities work, the problems that they encounter, and how their functioning can be improved.

II.LITERATURE REVIEW

The early literature on research ethics had its roots in international guidelines like the Nuremberg Code (1947), the Declaration of Helsinki (1964), and the Belmont Report (1979), which laid emphasis on auotnomy , beneficence, and justice. These international declarations formed the basis for Institutional Review Boards (IRBs) across the world. In the Indian context, the Indian Council of Medical Research (ICMR) has played the lead role in formulating ethical guidelines, and this reached its culmination in the

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National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Authors like Beauchamp and Childress (2013) have contended that ethical principles of respect for persons, beneficence, non-maleficence, and justice should regulate human subject research all over the world. Though these principles are increasingly being acknowledged in India, literature points out that their application to Indian universities, particularly beyond the medical space, is inconsistent and in fragmented forms.

Rashmi Kadam and Shashikant Karandikar (2012) highlighted in their research that ethics committees play an important role in the regulation of clinical research at the local level. However, it is seen that many ECs are oblivious to their roles and responsibilities. It is reported that ECs lack standard operating procedures, do not have a proper composition or adequate representation, thus affecting their functions in regulating clinical research. Moreover, ECs seem to function in isolation, as self-sufficient bodies, having no communication with the regulatory agency or other ECs. This brings forth the need for ECs to come together and share their experiences and observations, with the aim of updating themselves and refining their functions. Efforts also need to be focused on capacity building, centralized registration of ECs, and bringing an oversight mechanism in place. The Ethics Committees in India need to work in close association with forums such as the Forum for Ethics Review Committees in India and the Forum for Ethical Review Committees in Asia Pacific, in an effort towards empowering themselves.

Mukta S Kuyare, Santosh R Taur, And Urmila M Thatte (2014) research highlights the extensive variation in the operation of Ethics Committees among Indian institutions. Their research, conducted through interviews with researchers and members of IRBs, suggests that though IRBs may be on paper in most institutions, their practices are underdeveloped in response to a lack of training, infrastructural resources, and administrative will. Likewise, Ravindra B. Ghooi (2014) draws attention to the fact that the function of IRBs is critically reliant on institutional culture, the competence of its members, and the backing of university administration. Some universities have developed effective online systems and templates for ethics submissions, but others still process applications manually, leading to delays and lack of transparency. These studies call for capacity-building initiatives and standardization of review protocols to ensure fairness and quality.

Though a great deal of the IRB literature has been directed towards biomedical research, emerging research obligations draws attention towards ethical concerns in qualitative, participatory, and fieldwork in the social sciences. These call to mind how IRBs do not necessarily recognize the complexities of non-clinical studies, especially where these include ethnography, oral history, or community-based participatory research. In those situations, the inflexible biomedical model of informed consent can be unsuitable or even detrimental. Scholars promote ethics review processes that are attuned to social, cultural, and contextual realities. In India, where researchers frequently engage with marginalized and linguistically varied groups, the literature emphasizes the need for culturally appropriate consent processes and locally grounded ethical reflexivity.

Various studies identify the absence of formal training in research ethics as the key inhibitive factor to ethical adherence among Indian universities. Studies revealed that the majority of doctoral students in Indian universities had no access to formal courses or workshops on research ethics. This shortage translates into low-quality IRB submissions and, at worst, unethical activities like fabrication or omission of data or failure to obtain informed consent. The literature in the US, UK, and Australia indicates that incorporating ethics teaching into coursework makes a significant difference in improving ethical sensitivity and adherence. Indian researchers advocated for incorporating research ethics into postgraduate and undergraduate courses to promote ethical thinking at early stages of academic education.

The function of regulatory agencies like the University Grants Commission (UGC) and ICMR in influencing institutional ethics practices has been discussed in many policy and scholarly articles. A UGC (2023) report emphasizes the importance of research integrity and recommends compulsory setting up of Ethics Committees in every higher education institution. But studies indicate that compliance is low in non-medical institutions, partly because of the absence of enforcement mechanisms and partly because of institutional lethargy. Researchers are critical of tokenistic implementation of IRBs across numerous universities, observing that unless accountability, monitoring, and unequivocal policy mandates are enforced, IRBs risk being symbolic instead of being functional. There is a growing consensus in the literature that Indian ethics governance needs more robust policy alignment, funding, and national systems of oversight.

III.THE EVOLUTION AND LEGAL STRUCTURE OF IRBs IN INDIA

The idea of institutional ethical review originated from the experiences in the post-World War II and World War II era where unethical research activities were exposed. Historic pronouncements like the Nuremberg Code and Declaration of Helsinki put significant weight on informed consent and the ethical handling of human subjects during research. These international norms later percolated to influence the establishment of ethics review processes in nations such as India.

In India, the research ethics regulatory system has developed mainly through efforts on the part of the Indian Council of Medical Research (ICMR). The ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) offers the most detailed and best-accepted norms for ethics review in biomedical and health-related research. These guidelines aim to be broadly applicable to studies in addition to clinical trials, such as psychological, epidemiologic, and behavioral research. For drug and clinical research, the Drugs and Cosmetics Rules (1945) revised in 2013 mandate that all such Ethics Committees used to review such research are registered with the Central Drugs Standard Control Organization (CDSCO). For social sciences or non-clinical academics, there is no such centralized enforcement system, though the University Grants Commission (UGC) and universities are increasingly acknowledging the need for ethics committees across subjects.

IV.STRUCTURE AND COMPOSITION OF INSTITUTIONAL REVIEW BOARD

The basic function of an IRB is to perform rigorous ethical reviews of all research proposals for studies involving human participants. The process of reviewing such research proposals involves the close scrutiny of the research design, methods of recruitment of participants, data collection protocols, consent mechanisms, and mechanisms for maintaining confidentiality and protecting data.

One of the most important components reviewed by IRBs is informed consent procurement. Ethics committees have to ensure that researchers give participants transparent, detailed, and clear information regarding the reason for the study, processes, risks, advantages, and their ability to withdraw at any moment. For multilingual cultures such as India, where local languages may differ from English, it is essential to translate consent forms into local languages and clarify them to participants, especially those belonging to marginalized or vulnerable groups. IRBs also have the duty to evaluate the risk-benefit ratio of the research. If a study presents more than minimal risk to subjects but no direct or societal benefit, the study can be rejected or returned for revision. Research involving vulnerable populations—children, elderly, disabled persons, pregnant women, or economically underprivileged individuals—needs increased ethical scrutiny and extra controls.

Aside from the initial review of proposals, IRBs are supposed to check on ongoing research activities. This involves reviewing regular progress reports, confirming that deviations from the protocol are reported, and conducting an audit if required. This function of the IRB, however, is inadequately accomplished as a rule because of logistical difficulties and manpower shortages.

V.INSTITUTIONAL PRACTICES AND CASE EXAMPLES FROM INDIAN UNIVERSITIES

Some Indian universities have made considerable progress in establishing good and transparent IRB systems. Jawaharlal Nehru University (JNU) in New Delhi, for example, has a single central ethics committee that requires ethics review of all doctoral and sponsored research that involves human subjects. The process is clearly documented, and the university makes available guidance documents and templates to help researchers comply with ethical requirements.

Tata Institute of Social Sciences (TISS), Mumbai, has a very socially and participatory research-oriented ethics committee. With its commitment to working with marginalized groups, the committee is chaired by community members and ensures that there is respect for social justice and equity principles in research practices. There is encouragement to take a participatory style of research, and there is strong contextual sensitivity.

The University of Hyderabad has a centralized ethics committee that monitors ethical compliance on a departmental basis. Interviews with doctoral candidates indicate, however, that there is still uncertainty regarding ethical review processes, especially in non-medical departments. Although guidelines are available, their circulation and compliance are reported to vary from faculty to faculty.
These instances identify that although ethical monitoring is being institutionalized more and more, the extent of implementation and effectiveness differs quite noticeably among universities.

VI.EFFECTIVENESS OF IRBS IN THE INDIAN CONTEXT

The increasing presence of IRBs in Indian universities is a welcome trend and a sign of growing compliance with ethical standards. Yet their efficacy is still patchy. In institutions where there are established guidelines, trained personnel, and administrative backup, IRBs have been found to work effectively in protecting the participants and enhancing the quality of research. In such a setting, researchers are more likely to see the ethics review as a useful step and not as a bureaucratic obstacle. However, most universities do not possess the materials, infrastructure, and training to operate a fully operational ethics committee. Ethics review is relegated to a procedural exercise in some institutions, and proposals are approved without proper scrutiny. In other institutions, delays in review timelines because of understaffing or the absence of digital infrastructure discourage researchers from taking the process seriously.

Second, effective monitoring after approval is seldom of high quality or even exists. Interim reviews, follow-up audits, and exit reports are not often submitted or read, which devalues the concept of ethical oversight as a long-term obligation.

VII.CHALLENGES FACED BY INSTITUTIONAL REVIEW BOARDS

IRBs in India encounter a number of systemic and functional challenges. The most typical challenge is the inadequacy of administrative support. Most IRBs have inadequate staff, and hence it is challenging to handle a huge number of proposals or follow-up review. Consequently, review cycles can take longer than necessary, which becomes frustrating for the researchers.

A related but broader challenge is the lack of uniform procedures at institutions. Although ICMR guidelines are made available, universities may interpret and apply the guidelines in their own ways. The absence of a uniform approach creates inconsistency in review quality and makes it confusing for researchers, especially those working on collaborative, multi-institutional research.

Student and early-career researcher awareness and knowledge of research ethics are also low. In most universities, courses on research methodology cover ethical considerations if at all, and students are left to figure out how to go through the process on their own. This means subpar submissions to IRBs and occasionally results in unethical research being done without review.

Conflicts of interest also threaten the impartiality of IRBs. Where committee members have close ties to principal investigators or funding agencies, the integrity of the process may be undermined. Mechanisms for transparency and accountability are required to deal with this.

Digital research creates new complexities. Internet surveys, cellphone-based data collection, and the employment of artificial intelligence and big data in research create new ethical issues involving privacy of data, digital consent, and cybersecurity. IRBs are not ready to examine these aspects in detail.

VIII.RECOMMENDATIONS FOR STRENGTHENING IRBS IN INDIA

In order to meet these challenges, a number of steps are needed. First, regular training programs should be put in place for members of IRBs and researchers. These should include not just classical research ethics but also future-looking concerns such as digital ethics and data protection.
Second, the design of an online, centralized platform for ethics review can automate the application and tracking process. This would also make it easy to achieve consistency and transparency across institutions. The platform may come preloaded with templates, guidelines, tracking tools, and audit logs.

Third, ethics committees must be mandated in all academic fields, not only the health sciences. Universities must be incentivized to include ethical review of all research, and funding agencies must require demonstration of IRB approval before grant disbursement.

Fourth, increased community participation is necessary, particularly where research affects particular social or cultural groups. This would increase relevance and ethical strength of the research.
Lastly, there should be ethics education incorporated into the curricula of universities at undergraduate and postgraduate levels. If researches are trained early enough to be ethical in their thinking, the value and integrity of their research will be improved immensely.

CONCLUSION

Institutional Review Boards are the backbone of ethical research that help prevent human subjects from suffering and maintain the integrity of academic work. In India, the growing establishment of IRBs in universities is a welcome trend but has miles to go. The functioning of these committees ranges enormously, and they tend to be plagued by severe operational, administrative, and ethical issues. By meeting these through training, policy changes, infrastructure for digitalization, and increased public participation, India can establish a stronger, more accountable, and ethically responsive research environment commensurate with national as well as international standards.

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