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MEDICAL RESEARCH ETHICS IN PAKISTAN: THE NEED TO STRENGTHENED LEGAL OVERSIGHT

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Abstract
The lack of legal protection has posed a huge mess for medical research ethics in Pakistan. There is very low institutional control with no enforcement and many researchers do not know about ethics. There are international guidelines (Declaration of Helsinki, CIOMS) but not necessarily at the local level. Pakistan also has some regulations such as the Pakistan Medical and Dental Council (PMDC) guidelines and National Bioethics Committee (NBC); but these regulations are not implemented in all institutions. Biomedical research has a quality and security problem. Ethical Conduct Concern: Concerns about unethical conduct arise: Inadequate informed consent procedures, Inadequate protection of vulnerable groups. There is a need for better legal regulation to strengthen the ethical compliance, safeguard the rights of participants and build greater public confidence. This can be achieved through new legislation, effective oversight bodies, obligations, ethics training and regular assessment of research institutions. A common national framework will make ethical innovations on the basis of international guidelines and create reliable medical and scientific atmosphere in Pakistan.

INTRODUCTION

Medical research is important to promote medical knowledge, develop new treatments and improve population health (Sherin, 2023). However, the research ethical aspect is very important to maintain the safety of humans involved in the study and maintain their rights and dignity (Shaikh & Ali, 2023). The principles of biomedical research are internationally recognized in the ethical framework of the Declaration of Helsinki, Belmont report, and CIOMS guidelines.Internationally, the ethical principles of biomedical research are recognized in the ethical frameworks of the Declaration of Helsinki, the Belmont Report and CIOMS guidelines (Ahmed & Williams, 2023). These documents differentiate on principles such as informed consent, confidentiality and protection of vulnerable populations (Coleman et al., 2025).

These principles, as in most countries, have been incorporated in enforceable legal systems, the worrying case in Pakistan being the sporadic oversight and erratic practice of ethical principles (Jafarey et al., 2023). The Pakistan Medical and Dental Council (PMDC), the National Bioethics Committee (NBC) and Institutional Review Boards (IRBs) in Pakistan are also responsible for the ethical regulation of the country. However,

such institutions do not always possess the authority, resources and even legal reinforcements to ensure compliance (Qadri et al., 2024). The research studies face challenges such as poor monitoring of clinical trials, weak procedures of informed consent, and limited responsibility for ethical violations (Asif & Baig, 2023).

Furthermore, there are legal gaps to address new challenges such as genetic research, information privacy and commercialization of participants (Hayat et al., 2024). Medical research in Pakistan is a big issue and it needs to be managed by law to be improved. Research: The link between ideals and reality is the development of a single national law as well as the support of enforced regulations, frequent ethics training, and strong monitoring agencies (Sohail, 2025).

Research Justification

Ethical conduct in medical research is essential to the protection of human subjects of medical research and to sustaining people's faith in the future of scientific progress. In Pakistan, there are institutional review boards and national guidelines, but the ethics are not always followed and there are numerous gaps in ethical compliance. The different research settings, the institutional capacity and lack of adequate training in bioethics cause the unequal application of ethical standards. In addition, the growing number of clinical trials, public health research and private sector research has led to an increased need for regulatory systems to monitor more complex operations. This points to the need for stronger legal control in order to institutionalize roles, establish penalties for infringements and align national actions with international standards. The authority of ethics committees would also be clarified and consent procedures would be mandatory even for vulnerable groups who are typically recruited into research because of their socioeconomic status. Better supervision can reduce the risk of ethical failures such as poor risk reporting, lack of social interaction or poor information-security controls. With the passage of time, a strong legal system would enhance the level of openness, good research practices and more collaboration with other countries because of Pakistan's display of ethical integrity. This argument points to the necessity of having inclusive and enforceable laws to safeguard the participants and to promote sustainable biomedical innovation. The reforms are needed to create fair practices, and to strengthen the credibility and integrity of national and international research in the long term.

Literature Review

Pakistan has experienced a phenomenal rise in medical research in the past few decades however, there has not been any credible system of ethical regulations (Jafarey et al., 2023). Most academic Centres have institutional review boards. These are often not uniform, transparent and accountable. Both researchers and participants describe a lack of opportunities for informed consent, an ambiguous risk-benefit analysis, and insufficient privacy protection. Such an imbalanced ethical situation is usually caused by the inadequate institutional capacity and the lack of knowledge about research ethics among the stakeholders (Qadri et al., 2024). According to local studies, some of the oversight committees are not provided with formal charters, standard operating procedures and periodic external audit (Sharif & Hajra, 2025). Researches can be carried out without a formal ethical clearance for studies or projects which are not formally organized or funded by the government (Asif & Baig, 2023). When participants are not well informed and do not participate in the consent processes, they are at risk of pressure or exploitation, especially those who are part of vulnerable groups (Sohail, 2025). Without strong legal regimes and enforcement mechanisms, the remedial measures for improper conduct are often few and far between and the effort to deter abuse of conduct is minimal (Ahmed & Williams, 2023).

Objective guidelines on acceptance, confidentiality and trial registration would be provided through stricter legal control, reducing uncertainty and hence the lack of confidence (Asif & Baig, 2023). Regular inspections and legally mandated ethics committee accreditation would lead to greater uniformity across institutions

(Shaikh & Ali, 2023). Their participation in the debate on the approved trials and their results would be responsible behavior and would increase their Responsibility (Hayat et al., 2024). Penalty powers by a national regulatory body (NRA) would deter participants (Jafarey et al., 2023).

Moreover, there are going to be particular principles that are appropriate to the local culture and social environment to ensure that ethics review does not breach the community's values but rather promotes the global ethical standards (Qadri et al., 2024). An informed ethical culture needs training for researchers, ethics committees and institutional administrators (Sohail, 2025). Finally, more legal regulation will increase professionalism, respect human subjects and increase people's trust in medical studies (Asif & Baig, 2023).

Historical Context of Medical Research Ethics in Pakistan

The medical research ethics in Pakistan are highly linked to its development context of health, and slow transition from local traditions of bioethics to global norms (Ahmed & Williams, 2023). The early decades after independence were also marked by a lack of regulation of medical research. These were seldom developed and in the context of British medical practice, they solved moral dilemmas (Sharif & Hajra, 2025). The change from informal research ethics to more formal research ethics was gradual, but the level of ethical awareness did not rise to as high a level as before (Jafarey et al., 2023). Therefore, a National Bioethics Committee (NBC) was constituted in 2004 and it formulated Pakistan's first ever National Ethical Standards for Biomedical Research.

For the first time, the country attempted to conform to the universal moral principles such as autonomy, beneficence and justice and rationalize the concept of research governance (Sohail, 2025). IRB's were then established in hospitals and universities but the structure and working of each institution were different (Asif & Baig, 2023). However, little progress has been made in the implementation of the rules as they are not legally binding (Hayat et al., 2024). The growth of clinical trials and foreign investment in Pakistan raised the need for stronger standards and resulted in more in-depth discussions on the need for national ethical regulation for medical research (Shaikh & Ali, 2023) .

Theoretical Context of Medical Research Ethics

Ethics of medical research stems from a set of philosophic, legal and professional theories that guide the conduct of medical research with human subjects. The most basic value of it is the principle of respect to persons which is based on deontological ethics, i.e. autonomy, informed consent, and inherent dignity of each person. It is also guaranteed by the Hippocratic tradition of "beneficence" and "non-maleficence" and the utilitarian logic, so that the researcher might maximize the possible benefits and minimize the possible harms.

The other theory behind it is a justice theory which is based on distributive and social contract justice. This allows the diverse participants to be sufficiently represented, to distribute the risks/benefits equitably and to protect the vulnerable groups . Research ethics also follows the evolution of the human rights discourse that developed as a reaction to previous abuses that highlighted the necessity of global principles and standards. These theories are interpreted into practical guidelines in form of documents like Nuremberg Code, Declaration of Helsinki and the Belmont report.

However, current views do not dismiss this, but recognize the importance of bioethics based on transparency, scientific integrity and community involvement, especially when it comes to the field of research of global health. Other ethical research issues today are genetic research , AI driven health data and cross culture application to ensure that ethical tenets of the theory are adaptable and that medical science in general does not affect the wellbeing of humanity.

Laws Regarding Medical Research Ethics in Pakistan

Medical research ethics laws in Pakistan can provide systematic framework to protect human subjects, ensure integrity of research process and

hold researchers accountable. The heart of this structure is the Constitution of the Pakistani government which guarantees such fundamental human rights as dignity, privacy and protection from harm, which are the ethical foundation of any biomedical research. The Drug Regulatory Authority of Pakistan is the main regulating body in the country which regulates clinical trials, needs prior approval and makes sure that research conducted on pharmaceutical products is safe and ethical.

Other big institution is Pakistan Health Research council which is responsible for ensuring ethical standards, reviewing research proposals and ensuring that human subject are treated with dignity and fairness. The study protocols need to be reviewed by Ethical Review Committees at universities, hospitals and research facilities, and the committees are bound by law to review the protocols to ensure the study is based on voluntary informed consent, is anonymous and has a good "risk/benefit ratio. These committees also have control during the course of the study where adverse events are reported and addressed appropriately.

In Pakistan there is a legal framework which tries to have informed consent as one of the principal conditions. The participants should be well aware of the objectives, methods, risks and benefits of the study. Special care should be taken for vulnerable populations such as children, prisoners and people with poor decision-making ability. The laws also point out the cultural sensitivity that obliges the researchers to follow the local customs and religious beliefs when carrying out studies. The laws also say that personal health information must be protected by having safe data management procedures in place.

Challenges for Medical Research Ethics in Pakistan

Ethical issues in medical research in Pakistan involve a host of old and new issues that pose major challenges in the protection of human research subjects and the promotion of ethical scientific research. There is in one sense great difficulty in enforcing the ethical guidelines. The National Bioethics Committee has provided a number of frameworks that different institutions can adhere to, however many institutions still do not have very well developed internal review boards and the capacity to implement the standards in a uniform manner. Lack of regulation is likely to result in inconsistencies of approval procedures and poor oversight of ongoing research.

The second big issue is that there is little consciousness amongst the researchers, health workers and the participants. Most researchers have no formal training in research ethics and potential participants may not fully grasp consent forms, particularly if the population is less educated (e.g. rural). This violates the principle of voluntary participation and may expose the participants to risks of exploitation. Resource limitations are another factor that influences ethical compliance. The lack of funds in hospitals and universities can lead to a superficial approach to the processing of the data, to the security of the participants and to the respect of their confidentiality, favoring the research results over the ethical guidelines. Financial considerations may also drive speed, not ethics, in international collaborations.

There is also complexity in the social and cultural dynamics. Doctors and patients have a power dynamic that can make it less likely that patients will ask questions or refuse. The right to consent may be subject to limitations, especially in the context of family influence on gender conventions. Also the growing role of private pharmaceutical trials and questions of transparency and conflict of interest. The vulnerable populations can be enrolled in the study without proper safeguards. Compensation and follow-up treatments without proper supervision.

Pakistan needs to have better institutional ground, bioethics education and wider awareness and uniform national guidance of medical research for it to be scientifically and ethically responsible. It is also important to improve cooperation between policymakers, educational and community organizations as cooperation will help to build trust, provide resources and develop sustainable systems to maintain ethical integrity in the research process in Pakistan.

Opportunities for Medical Research Ethics in Pakistan

The rapid modernization of biomedical research, clinical trials and population health programs in Pakistan has led to the emergence of medical research ethics as a common phenomenon in Pakistan. Such a changing environment provides a number of opportunities to raise ethical standards and to create a more responsible research environment. One of the greatest opportunities is to increase the capacity of Institutional Review Boards (IRBs). The additional resources and training will better position the IRBs to review the research proposal and safeguard the participants. This will ensure there is more publicity and the local research will be more valid. Another avenue is to incorporate bioethics education into the curriculum of medical and health sciences. Ethics has been implemented in many places in universities but the expansion of this course and practical teaching based on cases can lead to a future researcher with ethical awareness. Ethical awareness can be developed through academic training but also through other means. There are professional development workshops for practicing physicians and researchers, where both groups can build ethical awareness in their professional life. The maturing digital health sector may also be grappling with new ethical challenges around data privacy, AI in healthcare and telemedicine.

The explicit national policies on digital health research will make Pakistan the leader of responsible innovation in the region. Also civil participation is a great opportunity. Community involvement in research planning and dissemination may improve informed consent, reduce misperception, and ensure local health relevance of the research. "More opportunities working with international institutions. Pakistan will be able to align its ethical practices with the best practices in the world, and be flexible in the local cultural context through other capacity building programmes and knowledge sharing.

There are also opportunities for strengthening regulatory authorities, especially with respect to clinical trials and pharmaceutical research to ensure transparency, participant protection and encourage ethically sound global studies. Overall, Pakistan has a unique position because of investment in education, capacity building, regulation and community involvement which will lead to quality, ethical research benefiting the society.

Discussion

In Pakistan, there are more and more complex studies being conducted with a health focus and the ethics of medical research is getting increasing attention. There are institutional review boards and guidelines, but implementation and enforcement are still high including those of the Pakistan Health Research Council. There are only a few research institutions which have full-scale ethics committees, and even then they are not always as able, independent or as rigorous in their review. It leads to unequal protection of the research participants, especially the vulnerable groups, who may not have a clear understanding of the risks and impact they may face as a consequence of participation. There is a need to strengthen legal control to fill these gaps.

There is more institutional focus on ethical review than is present in national legislation at the moment. Clear rules for informed consent, safety, data protection and accountability would ensure consistent ethical practices in all research settings. Moreover, the legal framework should stipulate the registration and auditing of ethics committees, including penalties for non-compliance, and ensure disclosure of clinical trials and biomedical research. The better legal regulation should be accompanied by capacity building e.g. for healthcare professionals, ethics committee members and researchers. Improving the legal framework and ethical literacy will ensure the promotion of scientific knowledge and the preservation of human dignity and rights and will improve the research environment in Pakistan.

Conclusion

Medical research ethics in Pakistan is one of the most challenging as guidelines are not always followed, medical research ethics committees are not so efficient and safeguarding the subjects of research is not warranted. While there are usually

Institutional Review Boards, they are not always effective because of a lack of uniformity, oversight and accountability. Therefore, there is need for enhanced law enforcement if there is to be a standard of ethical behaviour in the country. We need to have detailed laws that deal explicitly with informed consent, participant safety, privacy of participants' data, transparency in clinical research and have mechanisms for auditing and enforcing compliance with these laws.

In addition, capacity building initiatives are required to educate researchers, members of ethics committees and medical practitioners on ethical best practices that should be integrated into the legal reforms. Good legal frameworks and improved ethical literacy will enable Pakistan to promote responsible and accountable medical research to safeguard the rights of the participants and also to promote scientific innovations in an ethical manner, consistent with international ethical standards. This is the way to win the trust of the general public and to develop viable and quality research..

Recommendations

Legal measures should be taken to regulate the ethics of medical research in Pakistan. Government should empower medical research more ensuring safety of research subjects, scientific integrity and confidence of society. Institutional review boards are not uniformly available across the country and are not always available. A more coherent legal framework would help to harmonize the process of ethical review, narrow the gap in the decision making process and clarify the roles of researchers.

First of all, Pakistan needs to have a clear definition of standards and ethics in biomedical and social health research including ethical principles, procedure of risk and benefit assessment, security of data and how to achieve continuous monitoring.To start with, Pakistan needs a clear definition of standards and ethics in biomedical and social health research, including ethical principles, procedure of risk and benefit assessment, security of data and how to achieve continuous monitoring.

Secondly, the national regulatory authority should be empowered to audit ethics committees, demand changes where necessary and sanction violations. It should include mandatory registration and accreditation of all ethics review committees and their capacity to meet the internationally accepted standards. Third, to further develop competencies and the culture of responsibility, mandatory research ethics training for investigators, reviewers, and administrators should be established. Public transparency can be improved by registries of approved studies and annual reports of the oversight's activities.

Finally, adequate funding and resources are critical for proper implementation. If they are not backed by strong legal, administrative and educational support, ethical guidelines are only dreams. In the long run the proper supervision will protect the vulnerable groups, improve the quality of research and speed up the research situation in Pakistan to the ethical limits of the world for the achievement of the long term ethical development.

Research Limitations

There are also few limitations in medical research ethics in Pakistan which make it difficult to argue for better legal control. First, there is no good quality national information on the performance of ethics committees, so system weaknesses cannot be assessed. Second, IRBs differ in their composition, their skill and their power, making comparison difficult. Third, many studies are based on self-reported practices, which may result in an understatement of noncompliance and institutional pressures. Fourth, it is difficult to obtain the internal review documents, which adds to the lack of transparency and lack of an opportunity for the researchers to make an objective evaluation of compliance with the ethical standards.

Besides, there may be the problem of political sensitivities and bureaucratic barriers that may discourage investigators from a critical view of regulatory loopholes. The extent and the profundity of the empirical research is also limited by the availability of resources, in particular within the institutions of the public sector. Finally, there

is no national law, no uniformity in definitions or conclusions that can be generalized, and no law enforced to bring about reform. Such limitations highlight the need for deeper, more integrated research across all institutions across the country.

Research Implications

The improvement of legal regulation of medical research ethics in Pakistan has implications for policy, practice and public trust. Ethical review procedures to be standardized and made legally binding in all institutions to protect the participants and to hold the researchers accountable. To policy makers, more regulation is a mark of aligning national policies with international standards, which can then be collaborated with and can access more funds; and that there are fewer ethical uncertainties. Strong legal systems can be used in a clinical setting to improve the quality and reliability of research and thus promote evidence-based practices and the protection of vulnerable groups.

There are definite legal requirements for academic institutions which promote capacity building including training of ethics committees and investigators to foster a culture of ethical responsibility. At the societal level, open legal measures can be used to build societal trust in medical research that will enable participation and engagement in medical research. Overall it is not only regulatory but also trans-formative as inclusion of good legal control will ensure integrity of research, protect the human subjects and the medical research environment in Pakistan will be at par with international ethical standards.

Future Research Directions

Future research on the ethics of medical research in Pakistan should try to evaluate, update and implement the existing legislation for the sake of safety of the research participants and integrity of the research. A comparative analysis of the effectiveness of ethics committees in different institutions, both private and public, can help to identify points of weakness in compliance, capacity and the consistency of decisions. Research on the application of international ethical standards on local grounds will illuminate the issues of infusing international standards with local practices.

Research on the effectiveness of training compulsory investigators and reviewers can guide policy on capacity building. Also the results of the general population awareness and perception about research ethics can be utilized to create a research ethics awareness plan for increasing transparency and trust. A legal study of current regulatory policy and governance is necessary for this purpose. Finally, a longitudinal study to track the impact of improved legal regulation of research quality, participant safety and institutional accountability will provide empirical evidence to support sustained policy action that promotes ethical advancement of medical research in Pakistan.

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