

ETHICAL AND LEGAL DIMENSIONS OF CLINICAL TRIALS IN PAKISTAN: PROTECTING VULNERABLE POPULATIONS

Muhammad Suhail Akhtar^{*1}, Dr. Tansif Ur Rehman², Dr. Aisha³

^{*1}Department of Law, Dadabhoy Institute of Higher Education, Pakistan

²Teaching Associate, Department of Sociology, University of Karachi, Pakistan; and Visiting Faculty, Department of Law, Dadabhoy Institute of Higher Education, Pakistan

³Women Medical Officer, Civil Hospital Naushahro Feroze

^{*1}msuhail348@gmail.com, ²tansif@live.com, ³aishasolangi786@gmail.com

²<https://orcid.org/0000-0002-5454-2150>

Corresponding Author: *

Muhammad Suhail Akhtar

DOI: <https://doi.org/10.5281/zenodo.21030157>

Received	Accepted	Published
13 April 2024	24 June 2024	15 July 2025

ABSTRACT

The environment of Pakistan in terms of clinical trials has complicated ethical and legal issues that have a great impact on the vulnerable groups. Medical research has been increasing at a very high rate; therefore, there is a need to take more decisive actions, especially in societies that are not well-informed about their rights. Ethical problems with informed consent, community participation and even exploitation are ethical problems in poor and poorly-regulated areas. Some other issues that affect legal matters are implementation problems, lack of institutional capacity, and a lack of alignment between international and domestic ethical standards. While the regulatory framework in place in Pakistan is improved as compared to the previous one, its application is still lagging behind, with gaps in the guidance and ethics review system which makes it difficult to ensure equal protection. The weak populations (women, children, low-income patients, remote areas) continue to be more prone to being pressured or ill-informed in undertaking research. To ensure equality, trust and accountability in the clinical trial system in Pakistan, it is essential to strengthen the ethical governance, transparency and meaningful engagement.

Keywords: challenges, historical context, laws, opportunities, theoretical context

INTRODUCTION

Clinical trials are a key component in advancing medical knowledge, developing new treatments and improving human health in general (Memon et al., 2024). The increased importance of supporting healthcare with evidence-based practices has not only increased the importance of clinical research but also unveiled endless ethical and legal dilemmas in this system (Capulli et al., 2025). A poor level of awareness among citizens, a lack of socioeconomic drive, and inadequate

institutional setups pose a challenge to research participants, especially those who do not have access to quality information or proper healthcare services (Gonzalez-Blazquez et al., 2024).

Informed consent, risk disclosure, and participant recruitment are some of the areas, in which ethical issues may be raised. Due to their living in poorer or less fortunate communities, vulnerable groups are at a higher risk, including having less capacity to make informed consent and being more

vulnerable to coercion or undue influence (Mumtaz et al., 2024). There are also loopholes between the regulations and their implementation which give rise to additional complexities. The institutions' ability to ensure the safety of participants is weak because of the failure to implement the national guidelines consistently. A context like this will require another topic on the understanding and use of ethical standards to be studied (Memon et al., 2024).

There are also legal aspects that play a significant role in developing the clinical trial framework in Pakistan (Shaikh, 2024). Uneven compliance is caused by lax institutional supervision, uncertainty in the regulation, and uneven institutional capacity (Tolppa et al., 2024). The key steps in creating a system that respects the dignity, safety, and rights of all involved in the research are increased legal reporting, increased duties, and creation of a culture of transparency (Shaukat et al., 2024).

Research Justification

As medical research is growing at a fast pace and engaging more vulnerable groups, it is crucial to have knowledge of ethical and legal considerations of clinical research in Pakistan. In most societies knowledge about the research process is not well-developed and hence there is greater vulnerability to exploitation and inadequate release. From the analysis of these vulnerabilities, the researcher is able to identify the weaknesses in the system and propose solutions that will foster autonomy, transparency and respect in the process of enrolling the participants.

The other urgent justification is the dissimilarity between the regulatory structures and the real application. Pakistan has also put in place national guidelines and institutional review systems, which are not being applied consistently. Institutional capacity, committee function on ethics and monitoring systems create dissimilarities that have direct impact on the protection of participants. The gaps will be analyzed to gain insight into the improvement of the governance structures in order to improve accountability and to mitigate ethical risk. This study is also motivated by the fact that national practices should be brought to the

international ethical standards without interfering with the local cultural and social realities.

Given the rising trend of international cooperation, Pakistan needs to guarantee that clinical trials that are being performed in Pakistan have a high level of ethical standards. The benefits of taking into account the challenges and opportunities encountered will be to facilitate more efficient policy making, build trust in research institutions and participate in the development of a 'resilient ethical' clinical trial environment that will safeguard all participants, including those with a higher risk.

Literature Review

Research on clinical trials in the country, as it is also in the rest of the world, is highly dynamic but also very variable in terms of social, economic and institutional factors (Shaikh 2024). The number of clinical research has risen significantly due to an increasing number of partnerships between countries and the need to generate new innovations in healthcare in this country at low cost (Mumtaz et al., 2024). However, it has also uncovered gaps in moral preparedness, particularly in settings in which the regulation is weak or is failing (Gonzalez-Blazquez et al., 2024). Research has consistently argued for the need for explicit ethical guidelines, improved governance policies, and stronger supervisory mechanisms to better meet the needs of today's research practices in medicine (Lopez-Baron et al., 2024). Informed consent is one of the most complex issues in the ethics of abortion, and there is a lot of literature that deals with this issue. Poor education, language barriers and lack of a culturally competent communication methodology are reported as the main reasons for lack of information about trial procedures (Shaukat et al., 2024). Another aspect of therapeutic misconception is reported in the literature, referring to a scenario where the participants think that research will guarantee them some personal medical benefit (Memon et al., 2024).

Although there are already guidelines at national level, there is significant variability in how institutions implement these (Capulli et al., 2025). The literature review has already pointed out that strengthening ethics committees and developing

monitoring systems and legal pathways of accountability are required to ensure compliance (Kurihara et al., 2024). Overall, the literature suggests a system that is seeking to be improved, but yet has its own limitations due to insufficient enforcement, limited resources and institutional capacity and differences in institutional capacity, and for the Pakistani clinical research environment, the ethical and legal reform remains a priority.

Historical Context of Ethical and Legal Dimensions of Clinical Trials in Pakistan

The legal and administrative framework that was passed on under the independence period led to the development of the clinical trial environment in Pakistan. During the early days, regulations were shaped by the laws on the topic of public health of the colonial period, which did not directly relate to the ethics of research or the protection of subjects. Because of the growth in the number of medical institutions, there was informal clinical research, involving no particular ethics and a lack of control and responsibility (Shaukat et al., 2024).

Over the decades, the need to organize the research system increased as the sphere of medical science was developed and international cooperation was established (Memon et al., 2024). Consciousness of ethical issues increased due to the development of the global standards, which triggered the introduction of the basic review mechanisms in Pakistani institutions. However, the first steps were yet regional, which implied varying institutional capacities and the level of professional training (Khan et al., 2023).

The modern era brought greater attention to the rights of the participants, Informed consent, and the unification of the regulations (Memon et al., 2024). National guidelines were implemented in line with the international ethical standards, but the problems of implementation persisted (Mumtaz et al., 2024). The low monitoring rates and institutional independence still have an impact on the contemporary ethical and legal discourses of clinical research (Shaukat et al., 2024).

Theoretical Context of Ethical and Legal Dimensions of Clinical Trials in Pakistan

The legal and administrative framework that was passed on under the independence period led to the development of the clinical trial environment in Pakistan. In the early times, the laws concerning public health of the colonial era influenced the regulations, and these had nothing to do with the ethics of research or safeguarding the subjects. Due to the increase in the number of medical institutions, there was informal clinical research, which had no particular ethics, was without control and lacked responsibility. As the field of medical science expanded, and international cooperation was developed over the decades, the need for organization of the research system grew. The awareness of ethical issues was enhanced because of the evolution of the global standards, which led to the implementation of the basic mechanisms of review in the Pakistani institutions. However, the initial steps were still regional, and this meant that there were different institutional capacities and levels of professional training. Informed consent and the amalgamation of the rules were given more significance during the modern era, alongside an increased focus on the rights of the participants. National guidelines were implemented in line with the international ethical standards, but the problems of implementation persisted. The low monitoring rates and institutional independence still have an impact on the contemporary ethical and legal discourses of clinical research.

The ethical basis of clinical trials consists of classical theories, based on which moral reasoning is developed and the practice of scientists. As the concept of deontological ethics is applied to the problem of informed consent and autonomy demands of the participants, the emphasis on the concept of duty and respect, and the requirement of following the principles of morality is particularly relevant. Utilitarianism presents an alternative viewpoint, in which the maximization of the overall well-being is the main factor, and it is in the interest of the researcher to balance risks and benefits in such a way that maximizes the well-being of the most. Another interesting dimension is virtue ethics, another dimension that refers to character and integrity and the moral

responsibility of the researchers. It promotes the values of honesty, empathy, and fairness, which are values needed to make tough decisions in the clinical environment.

This is also supported by the justice theory that mandates equal distribution of the risks and benefits of the research systems, and their ability to safeguard the individuals from exploitation. These theoretical views contribute to the development of modern ethics in clinical research particularly in the case of vulnerable groups. They provide guidelines in the interpretation of the moral dilemma, evaluation of the institutional practices and to make sure that research is informed by dignity and fairness. Incorporation of these theories in regulations will enable Pakistan to enhance its ability of protecting the actors and supporting ethically sound research.

Laws Regarding Clinical Trials in Pakistan

1. Pakistani Regulatory Authority of Pakistan (DRAP) Act, 2012

The main law of the regulation of clinical trials in Pakistan is the Pakistani Regulatory Authority of Pakistan (DRAP) Act, 2012. It describes the responsibility of the institutions in approving the research protocol, observing the research sites and safety of the participants. Compliance with ethics is determined by requirements of the Act regarding registration, trial supervision and reporting.

2. Guidelines of Bioethics Committee (NBC): NBC guidelines give ethical principles used in conducting clinical research, such that informed consent, risk-benefit analysis, confidentiality as well as independent ethical review are done. These policies have required all institutions to come up with accredited ethics review committees that are in a position to review research proposals.

3. Ethical Review Committee (ERC) Regulations: ERC regulations are the stipulations which are applied while operating institutional review boards which are concerned with the protocol of the trials, observation of ongoing studies, and do not jeopardize the rights and well-being of subjects. The guidelines provide ideas on committee organization, independence of the

institutions, the supervision of conflict of interest, and systematic documentation.

4. Clinical Practice (GCP) Guidelines: Pakistan uses the guidelines of Good Clinical Practice (GCP) to enhance the authenticity of clinical studies, to ensure accurate data collection and to maintain ethical conduct of the human subjects in the clinical studies. These guidelines set the industry standards of operation of the investigators, sponsors and institutions.

5. International Ethical Standards: Pakistan follows such international standards as the Declaration of Helsinki and CIOMS in the organization of ethical management. These are instruments which allow for justice, transparency and the safety of the exposed subjects.

Challenges for Ethical and Legal Dimensions of Clinical Trials in Pakistan

Pakistan experiences a lot of ethical and legal dilemmas in regulating clinical trials, mainly because of structural weaknesses in the healthcare and regulatory systems. Among the most enduring issues, the lack of knowledge about research protocols on the part of the participants, in particular, low-income or marginalized groups needs to be mentioned. The presence of low literacy, access to information on healthcare, and socio-economic pressures tend to affect the choice to take part thus questioning the nature and quality of consent as voluntary. Lack of community engagement can also make it even more challenging to achieve ethical compliance, as, for example, the risks, benefits, and trial procedures may not be culturally understandable to a researcher. These problems lead to the result of unequal forces between the researcher and the participant, which puts at risk the possibility of inadvertent coercion. The other significant Issue is the lapses in the application of ethical and legal regulations. The national guidelines have a wide range of degrees of heterogeneity in how much they can be translated by institutions.

Most hospitals and research sites lack complete ethics committees and procedures for the review process, and individuals trained to supervise the trials in progress. Poor institutional coordination leads to coordinated efforts in the sense that it is

hard to create the same protection in all the trial sites. The general system can therefore have trouble imposing a sense of responsibility and consistency in ethics. Another obstacle is connected with regulatory loopholes and the ever-changing system of International cooperation. With more of the global pharmaceutical companies venturing into Pakistan, there have been concerns over transparency, data handling, and benefit sharing. Local regulatory authorities are prone to problems with complex trial designs or international standards. In addition, the weakest members of society may also be selectively recruited, as the costs of running the operation are less.

Opportunities for Ethical and Legal Dimensions of Clinical Trials in Pakistan

The development of medical studies in the country has a great prospect of reinforcing the ethical and legal bases of the clinical trial system in Pakistan as the country's healthcare industry keeps progressing and adopting modernization. The growing interest in evidence-based health care in the country has motivated the improvement of regulatory frameworks and ethics control. With the growing awareness of global standards, investigators can be further trained, specialized bioethics courses can be established and institutional review capacity of medical universities and hospitals can be expanded in Pakistan. Improved scientist-community collaboration can help ensure transparency and enhance the trust of how clinical research is carried out.

The other opportunity that can be taken advantage of is the changing regulatory situation in the country. Compliance was based on more transparent guidelines and compliance with international ethics tools is a good base to reinforce compliance. These reforms can assist the institutions in having a single countrywide approach to ethical governance and minimize differences in participant protection across areas. Involvement of more international collaborations is also an option which offers a beneficial path towards development of ethical and legal principles in clinical trial environment in Pakistan. Joint research projects offer the opportunity of

using the best practice, the latest scientific knowledge and the latest ethical practice. Joint ventures can facilitate the transfer of technology, enhance the data governance and stimulate transparency in clinical trials. With a proper utilization of these opportunities Pakistan can create a fair, trustworthy, ethical clinical research system which will benefit the vulnerable segments of society and provide scientific advancement as well.

Discussion

Clinical trials in Pakistan have a complex ethical and legal landscape that is associated with both positive and negative trends. Although it has been observed that there are national guidelines and regulatory bodies, their effectiveness is based on the fact that they are to be implemented consistently and on the institutional capability to enforce the international ethical principles. Ethical issues were more salient in the recent research area of health care research, informed consent was discussed less, and the transparency of research communication was questioned.

Conclusion

Ethical and legal issues in clinical trials in Pakistan is a complicated issue. While the national guidance and review processes provide a basic framework in which the recipients can be protected, the laws must be implemented strictly, and the institutions must be able to maintain the ethical standards. The growing number of clinical research also calls for the need to incorporate local details and particularities of the research site into those of global ethical rules and standards, and the well-being of those involved in clinical research should not be endangered by scientific advancement. The long-term commitments of morality and accountability in the new clinical trials regime will protect the rights of research participants and ensure trust in people of Pakistan.

Recommendations

To enhance the ethical conduct of the clinical trials in Pakistan, investment in the institutional capacity and periodic monitoring of the regulatory standards is needed. The research institutions ought to increase training on informed consent

procedures, risk communication, and participant rights. The acquisition of skills by investigators and members of the ethics committee will help enhance decision making and give the participants the information that is clear and culturally relevant. There is also a need to create awareness among the people to know more about their rights and the intention of clinical research, which can minimize the weaknesses associated with misinformation and power imbalances.

The regulatory bodies should be empowered to improve the regulation process to ensure equivalent application of ethical and legal requirements in all trial sites. These include strengthening of monitoring systems, implementation of standardized review systems, and empowering ethics review committee accreditation. The potential exists for developing more centralized digital tools of registration, reporting, and compliance monitoring to encourage transparency and accountability in trial operations. Better communication among institutions will contribute to removing the differences in the protection of recipients.

The partnership with the international community also offers more opportunities by conducting clinical trials in Pakistan. Pakistan may be able to operate its systems in line with the current international standards by embracing the global practices, enhancing the infrastructure of data management, and introducing a transparent benefit-sharing mechanism. These changes should be prioritized to ensure an environment for research that safeguards vulnerable populations, as well as a research environment that is ethically correct.

Research Limitations

Conducting research on legal and ethical issues of clinical trials in Pakistan is not such a simple task, there are a number of deep rooted and environmental barriers that will need to be overcome. There is significant limitation in the availability of credible data due to lack of uniformity of documentation, lack of transparency and lack of reporting rigor in institutions. Records at most trial sites are not standardized in order to gain accurate information regarding participant recruitment, quality of consent and monitoring

activities. Such loopholes limit the level of analysis and limit the possibilities of fully evidence-based conclusions.

The other limitation is due to the lack of local empirical research that is specifically on vulnerabilities in Pakistani research environments. Any consideration of ethical shortcomings may be deferred by moral laxity or political pressures and limitations. Also, the quick change in regulatory attitudes suggests that outcomes could be out of date soon.

Future Research Directions

A detailed study is required which will examine the cultural norms, socio-economic pressures and levels of literacy that can be included in the decision making process and their involvement in the trial. The establishment of national datasets and longitudinal studies could help to give a better picture of the changing face of ethical governance and what may need to be done to change it.

The other relevant area is the evaluation of the effectiveness of regulatory systems applied. The correspondence of the national level guidance with the international ethical standards will be evaluated and obstacles to full compliance identified. It would help in stipulating the best practices that can be applied in the Pakistani context as compared to other low and middle-income countries. Digital monitoring gadgets and trends with regards to community participation, as well as capacity building interventions that could improve ethical responsibility and safeguarding of vulnerable participants, should be investigated as well.

References

- Capulli, E., Druda, Y., Palmese, F., Butt, A. H., Domenicali, M., Macchiarelli, A. G., Silvani, A., Bedogni, G., & Ingravallo, F. (2025). Ethical and legal implications of health monitoring wearable devices: A scoping review. *Social Science & Medicine*, 370, Article 117685. <https://doi.org/10.1016/j.socscimed.2025.117685>

- Gonzalez-Blazquez, F. J., Lopez-Mora, C., & San Jose-Tarrega, J. (2024). Bioethical knowledge in students and health professionals: A systematic review. *Frontiers in Medicine*, 11, Article 1252386. <https://doi.org/10.3389/fmed.2024.1252386>
- Khan, S. J., Asif, M., Aslam, S., Khan, F., Khalid, A., Siddiqui, S. A., Atif, S., Alam, F., Mohamed, A. H., & Qadir, A. (2023). Pakistan's healthcare system: A review of major challenges and the first comprehensive universal health coverage initiative. *Cureus*, 15(9), Article e44641. <https://doi.org/10.7759/cureus.44641>
- Kurihara, C., Kerpel-Fronius, S., Becker, S., Chan, A., Nagaty, Y., Naseem, S., Schenk, J., Matsuyama, K., & Baroutsou, V. (2024). Declaration of Helsinki: Ethical norm in pursuit of common global goals. *Frontiers in Medicine*, 11, Article 1360653. <https://doi.org/10.3389/fmed.2024.1360653>
- Lopez-Baron, E., Abbas, Q., Caporal, P., Agulnik, A., Attebery, J. E., Holloway, A., Kissoon, N. T., Mulgado-Aguas, C. I., Amegan-Aho, K., Majdalani, M., Ocampo, C., Pascal, H., Miller, E., Kanyamuhunga, A., Tekleab, A. M., Bacha, T., González-Dambrasuskas, S., Bhutta, A. T., Kortz, T. B., Murthy, S., & Remy, K. E. (2024). Challenges in institutional ethical review process and approval for international multicenter clinical studies in lower and middle-income countries: The case of PARITY study. *Frontiers in Pediatrics*, 12, Article 1460377. <https://doi.org/10.3389/fped.2024.1460377>
- Memon, R., Asif, M., Shah, B. A., Kiran, T., Khoso, A. B., Tofique, S., Miah, J., Ahmad, A., Chaudhry, I., Chaudhry, N., Husain, N., & Edwards, S. J. L. (2024). Clinicians' experiences of obtaining informed consent for research and treatment: A nested qualitative study from Pakistan. *BMC Medical Ethics*, 25(1), Article 131. <https://doi.org/10.1186/s12910-024-01119-8>
- Mumtaz, H., Haider, S. M. A., Neha, F., Saqib, M., Nadeem, A., Fahim, A., & Allahuddin, Z. (2024). Clinical trials landscape in a lower-middle-income country (Pakistan). *Journal of Clinical and Translational Science*, 8(1), Article e7. <https://doi.org/10.1017/cts.2023.701>
- Shaikh, B. T. (2024). Universal health coverage in Pakistan: Exploring the landscape of the health system, health-seeking behaviours, and utilization of health services. *The Lancet Regional Health – Southeast Asia*, 27, Article 100440. <https://doi.org/10.1016/j.lansea.2024.100440>
- Shaukat, M., Imping, A., Rogge, L., Khalid, F., Ullah, S., Ahmad, F., Kibria, Z., Landmann, A., Khan, Z., & De Allegri, M. (2024). Un/met: A mixed-methods study on primary healthcare needs of the poorest population in Khyber Pakhtunkhwa province, Pakistan. *International Journal for Equity in Health*, 23(1), Article 190. <https://doi.org/10.1186/s12939-024-02274-5>
- Tolppa, T., Hussaini, A., Ahmed, N., Dondorp, A. M., Farooq, S., Khan, M., Masood, A., Murthy, S., Saleem, S., Shuja, Z., & Zaman, S. (2024). Establishment of a patient and public involvement and engagement group to support clinical trials in Pakistan: Initial lessons learned. *Research Involvement and Engagement*, 10(1), Article 98. <https://doi.org/10.1186/s40900-024-00635-6>