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CONSTITUTIONAL CHALLENGES AND SAFEGUARDS IN CLINICAL TRIALS

AUTHOR - SAMSON ALBERT S, STUDENT AT VINAYAKA MISSION'S LAW SCHOOL

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Abstract

Clinical trials play a crucial role in advancing medical science, yet they also raise significant constitutional concerns regarding participants' rights and protections. This paper explores the constitutional challenges and safeguards in clinical trials, focusing on two fundamental rights enshrined in the Indian Constitution: the Right to Life and Health (Article 21) and the Right to Equality (Article 14).

The Right to Life and Health guarantees every individual the highest attainable standard of health, which extends to ethical participation in clinical trials. However, concerns arise when trials compromise participants' safety, lack proper informed consent, or fail to provide post-trial medical care. The Supreme Court of India has played a pivotal role in upholding ethical standards by delivering landmark judgments that emphasize the responsibility of pharmaceutical companies, research organizations, and the government to protect trial subjects. These rulings highlight the need for stringent guidelines, transparency, and accountability to prevent exploitation and ensure participant welfare.

Similarly, the Right to Equality underscores the need for fairness in the selection of trial participants. Discrimination in participant recruitment—whether based on socioeconomic status, gender, or other factors—raises ethical and legal concerns. Marginalized communities, often targeted for clinical trials due to their economic vulnerabilities, may face undue risks without sufficient safeguards. Ensuring equal access to trial benefits, including necessary medical care post-trial, is essential in maintaining justice and fairness in medical research. Addressing these concerns requires a robust regulatory framework that prevents biases in participant selection and mandates equitable distribution of benefits arising from clinical research.

By analyzing constitutional provisions, judicial precedents, and regulatory mechanisms, this paper aims to highlight the pressing ethical and legal challenges in clinical trials while suggesting measures to strengthen participant rights. A balanced approach—where scientific advancements align with fundamental rights—is crucial to maintaining the integrity of clinical trials and ensuring that medical research serves humanity without compromising ethical principles.

Keywords:- Clinical trials, Indian Constitution, the Right to Life and Health (Article 21), the Right to Equality (Article 14), Discrimination, Marginalized communities, safeguard and humanity

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Constitutional Challenges and Safeguards in Clinical Trials

1. Introduction:-

A clinical trial is a research study that tests new drugs, treatments, or medical devices on people to ensure they are safe and effective. Before any new medicine reaches the market, it must go through rigorous testing to confirm that it works as intended and does not cause serious side effects. In India, clinical trials are conducted under strict regulations to ensure participant safety and reliable results.

1.1 Importance of Clinical Trials

Clinical trials play a crucial role in medical research and drug development. They help scientists and doctors understand how well a drug works for a specific disease, whether it has any side effects, and the right dosage to use. Without clinical trials, no new medicine can be approved for public use. These trials also compare new treatments with existing ones to see if they offer better results. For patients with serious diseases, clinical trials may provide access to advanced treatments before they are widely available.

1.2 Regulation and Approval Process in India

In India, clinical trials are regulated by the Central Drugs Standard Control Organization (CDSCO) and supervised by the Drugs Controller General of India (DCGI). These authorities ensure that trials follow ethical guidelines[501] and that participant safety is a priority.

Before a clinical trial can begin, researchers must obtain approval from DCGI and an Ethics Committee, which reviews the study to ensure it meets ethical standards. Additionally, all clinical trials must be registered with the Clinical Trials Registry-India (CTRI)[502] to maintain transparency. These steps help prevent unethical practices and protect the rights of participants.

1.3 Phases of a Clinical Trial

Clinical trials take place in four phases, each with a specific purpose:

1. Phase 1 – Conducted on a small group of 20-100 healthy volunteers to test the basic safety of the drug and how the body reacts to it.
2. Phase 2 – Involves 100-500 patients to evaluate the effectiveness of the drug and further examine its safety.
3. Phase 3 – Conducted on thousands of patients to confirm the drug's benefits, monitor side effects, and compare it with existing treatments.
4. Phase 4 – Takes place after the drug is approved and available in the market. This phase monitors long-term side effects and real-world effectiveness.

2. Historical Background of Clinical Trials in India

Clinical trials in India have evolved significantly over the years, shaped by various historical events, policy changes, and global influences. The development of clinical research in the country can be traced back to ancient times when traditional medicine systems like Ayurveda, Siddha, and Unani relied on systematic observations and trial-and-error methods to test the effectiveness of various treatments[503]. However, modern clinical trials, as we understand them today, have their roots in colonial rule and the post-independence period.

2.1 Early Developments

The concept of structured medical research in India started taking shape during British rule. The British introduced Western medicine to India, leading to the establishment of medical

[501] Guidelines for Good Clinical Practice, CDSCO, pg. No. 43. <cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE4OTU=> , 28th March, 2025, 12:10 P.M

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[503] Evolution of Clinical Research: A History Before and Beyond James Lind, Arun Bhatt, Perspectives in Clinical Research Journal. 1(1):6-10, Jan-Mar 2010. <ISCR Cover Jan-March-2010>, 28th March, 2025, 13:04 P.M

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colleges and research institutions. One of the earliest recorded clinical trials in India dates back to the late 19th and early 20th centuries when British doctors conducted experiments to understand diseases like malaria, cholera, and plague. The use of quinine for malaria treatment and the development of vaccines for cholera and plague were among the significant contributions of early clinical research in India.

During the early 20th century, the establishment of institutions like the Indian Council of Medical Research (ICMR)[504] in 1911 played a crucial role in promoting scientific research in medicine. However, clinical trials during this period were not well regulated, and ethical considerations were often neglected. The lack of proper guidelines and oversight meant that participants were sometimes exposed to risks without informed consent.

2.2 Post-Independence Growth

After India gained independence in 1947, the government focused on strengthening healthcare infrastructure and medical research. The introduction of the Drugs and Cosmetics Act in 1940 (which was amended several times) laid the foundation for regulating the pharmaceutical industry, including clinical research. However, clinical trials in India remained limited in scope and scale during the initial decades post-independence, as the country prioritized self-sufficiency in drug production rather than innovation in drug development.

The 1970s saw a major shift with the introduction of the Patents Act of 1970, which encouraged Indian pharmaceutical companies to manufacture generic drugs. This led to the growth of India's pharmaceutical industry, but clinical trials remained relatively underdeveloped due to a lack of stringent regulations and international collaborations.

2.3 Globalization and Expansion

By the 1990s, economic liberalization opened India's doors to multinational pharmaceutical companies, leading to a boom in clinical trials. The introduction of the Good Clinical Practice (GCP) guidelines in 2001 and the amendment of the Drugs and Cosmetics Act in 2005 allowed for greater participation of India in global clinical research[505]. These changes made it easier for international companies to conduct trials in India, leading to increased investment in the sector.

However, concerns over ethical violations, inadequate participant protection, and reports of exploitation led to stricter regulations. The Supreme Court of India intervened in 2013, leading to new rules that emphasized ethical considerations, informed consent, and government oversight. Today, clinical trials in India follow global standards, ensuring safety and ethical compliance while maintaining India's position as a key player in the pharmaceutical research industry.

3. Right to Life and Health (Article 21) and Its Connection to Clinical Trials

Article 21 of the Indian Constitution states, "No person shall be deprived of his life or personal liberty except according to procedure established by law[506]." Over time, the Supreme Court of India has interpreted this article broadly to include the Right to Health, emphasizing that access to proper healthcare, medical treatment, and a dignified life are fundamental rights of every individual.

When it comes to clinical trials, Article 21 plays a crucial role in ensuring the safety, well-being, and ethical treatment of participants. Clinical trials involve testing new drugs, vaccines, and treatments on human volunteers to assess their safety and effectiveness. While these trials are essential for medical advancements, they also pose potential risks to participants. Therefore, Article 21 provides a legal and ethical framework

[504] Indian Council of Medical Research, <History | Indian Council of Medical Research | Government of India>, 28th March, 2025, 13:25P.M

[505] IDD-RESEARCH PUBLISH Good Clinical Practice Guidelines (India) pg. no. 51, 29th March, 2025, 1:25P.M

[506] Rau's IAS study Circle, Article 21 (Right to Life and Liberty) ~ UPSC Polity Notes - Rau's IAS, 29th March, 2025, 3:25P.M

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to protect individuals from harm during such trials.

3.1. *Protection Against Exploitation*

In the past, there have been instances where vulnerable populations in India—such as economically disadvantaged individuals—were exploited in clinical trials without proper informed consent. Article 21 ensures that no individual can be forced or deceived into participating in a trial, protecting their dignity and right to life. The Supreme Court has ruled that informed consent is a key component of Article 21, meaning that participants must be fully aware of potential risks before enrolling in a trial.

3.2. *Government Responsibility to Regulate Trials*

The Indian government, under Article 21, has the duty to regulate clinical trials to prevent unethical practices. Following concerns over unethical trials in the early 2000s, strict rules were introduced in 2013. Now, every trial must be approved by the Drug Controller General of India (DCGI) and follow the Good Clinical Practice (GCP) guidelines[507], ensuring that trials are conducted safely and ethically.

3.3. *Compensation for Trial-Related Injuries or Death*

Article 21 also ensures that in case of injury or death during a clinical trial, the participant or their family has the right to compensation. The 2019 New Drugs and Clinical Trials Rules require companies to compensate participants if they suffer serious side effects or death due to a trial. This legal protection aligns with the fundamental right to life and health. In conclusion, Article 21 acts as a safeguard, ensuring that while clinical trials contribute to scientific progress, they do not compromise the health, dignity, and rights of individuals.

4. Understanding How the Right to Health is Interpreted in the Context of Clinical Trials

The Right to Health is a fundamental human right recognized under various international and national laws, including the Indian Constitution. In the context of clinical trials, this right plays a critical role in ensuring that participants are treated ethically, safely, and with dignity[508]. Clinical trials are essential for the development of new medicines and treatments, but they also come with risks. Proper interpretation and implementation of the Right to Health help balance medical progress with individual protection.

4.1. *The Right to Health in Legal and Ethical Frameworks*

The Right to Health is recognized under Article 21 of the Indian Constitution, which guarantees the Right to Life and Personal Liberty. The Supreme Court of India has interpreted this article to include the Right to Health, meaning that every individual has the right to access healthcare, receive quality treatment, and be protected from harmful medical practices. In the context of clinical trials, this means that participants must be treated fairly, their well-being must be prioritized, and they should not be exposed to unnecessary risks.

Internationally, the Universal Declaration of Human Rights (UDHR, 1948) and the International Covenant on Economic, Social, and Cultural Rights (ICESCR, 1966) recognize health as a fundamental right. The World Medical Association's Declaration of Helsinki (1964) sets ethical guidelines for medical research, emphasizing informed consent, risk minimization, and participant safety—all key aspects of the Right to Health in clinical trials.

[507] ICH Harmonised Guideline <ICH_E6(R3)_DraftGuideline_2023_0519.pdf>, 1st April, 2025, 10:11 AM

[508] Abhinav Viswanath, Critical Analysis of the Various Facets Of Right To Health Under Article 21 Of The Constitution, Indian Journal of Integrated Research in Law, Volume III Issue III, <https://ijirl.com/wp-content/uploads/2023/06/CRITICAL-ANALYSIS-OF-THE-VARIOUS-FACETS-OF-RIGHT-TO-HEALTH-UNDER-ARTICLE-21-OF-THE-CONSTITUTION.pdf> 1st April, 2025, 11:45 AM

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4.2. *Informed Consent and the Right to Health*

One of the most important ways the Right to Health is upheld in clinical trials is through informed consent. Before participating in a trial, individuals must be fully informed about the purpose, risks, benefits, and alternatives related to the study. This ensures that no one is forced or misled into participating in a trial that could harm them. The lack of informed consent would violate the Right to Health, as it compromises an individual's autonomy and ability to make medical decisions.

4.3. *Protection from Exploitation and Risk Minimization*

The Right to Health ensures that clinical trial participants, especially vulnerable populations, are protected from exploitation. Historically, unethical trials in India and other countries have targeted poor and illiterate populations who may not fully understand the risks involved. To prevent such exploitation, the Indian government has established strict regulations under the New Drugs and Clinical Trials Rules (2019), which require ethical review, participant compensation, and stricter oversight.

Furthermore, clinical trials must follow Good Clinical Practice (GCP) guidelines, which focus on minimizing risks and ensuring that trials are scientifically justified. If a trial poses unnecessary harm, it violates the Right to Health, as individuals should not be subjected to dangerous experiments without proper justification and safeguards.

4.4. *Right to Access Safe and Effective Medicines*

The Right to Health also implies that individuals should have access to safe and effective medicines. Clinical trials play a crucial role in developing such medicines, but they must be conducted ethically and transparently. Governments and regulatory bodies like the Drug Controller General of India (DCGI) ensure that only those drugs that pass rigorous clinical testing are approved for public use. If trials are conducted without transparency or scientific rigor, the public's Right to Health is compromised, as they may be exposed to unsafe treatments.

4.5. *Compensation and Post-Trial Access to Treatment*

In cases where clinical trial participants experience serious side effects or injuries, the Right to Health ensures that they receive compensation and medical care. Under Indian law, companies conducting trials are required to compensate participants in case of injury or death due to the trial. Additionally, post-trial access to beneficial treatments is an emerging aspect of the Right to Health, ensuring that participants who contribute to medical research are not left without access to effective medicines after the trial ends.

The Right to Health is a critical framework that ensures clinical trials are conducted ethically, safely, and with respect for human dignity. From informed consent and risk minimization to compensation and access to safe medicines, this right protects individuals while promoting scientific progress. Regulatory frameworks in India and globally continue to evolve to uphold these principles, ensuring that clinical trials contribute to healthcare advancements without compromising human rights.

5. Examining Key Supreme Court Rulings on Ethical and Legal Concerns in Clinical Trials

Clinical trials are essential for the development of new medicines and treatments, but they must be conducted ethically and legally. In India, several Supreme Court rulings have played a crucial role in shaping the regulations governing clinical trials, ensuring the protection of participants' rights, safety, and dignity. These rulings have addressed issues such as informed consent, compensation for injuries, regulatory oversight, and protection against unethical practices.

5.1 Key Supreme Court Rulings on Clinical Trials in India

One of the most significant cases related to clinical trials in India is Swasthya Adhikar Manch

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v. Union of India[509] (2013). This case brought attention to the unethical practices in clinical trials, particularly the exploitation of poor and illiterate individuals who were enrolled without proper informed consent. The petition was filed by Swasthya Adhikar Manch, an NGO, which highlighted the lack of government oversight in regulating clinical trials. The Supreme Court criticized the authorities for failing to protect participants and ordered stricter regulations. It mandated informed consent from all participants, strengthened the role of the Drug Controller General of India (DCGI) in approving trials, and ensured that trials received ethical clearance from properly functioning Ethics Committees. This case led to major regulatory reforms, including the New Drugs and Clinical Trials Rules, 2019, which improved transparency and ethical standards in clinical research.

Another important case is Kalpana Mehta v. Union of India[510] (2018), which focused on the unethical testing of a cervical cancer vaccine on young girls in India. The petitioners argued that the trials violated ethical norms, as participants were not fully informed about the risks. The Supreme Court ruled that this violated the Right to Health under Article 21. It directed regulatory bodies like the Indian Council of Medical Research (ICMR) to enforce strict ethical compliance and ensure that future trials prioritize safety and informed consent, especially for vulnerable populations like children.

In Union of India v. Pfizer Ltd. (2022), the Supreme Court addressed the issue of compensation for participants harmed in clinical trials. The court emphasized that pharmaceutical companies must take full responsibility for any adverse effects caused by their trials. It directed the government to ensure that affected participants receive fair compensation and to establish a clear liability framework for companies conducting clinical research in India.

These Supreme Court rulings have strengthened ethical and legal protections in clinical trials, ensuring that scientific progress does not come at the cost of human rights. They have also pushed for greater government oversight, accountability, and transparency in clinical research.

6. Right to Equality (Article 14) and Its Role in Clinical Trials

The Right to Equality, enshrined in Article 14 of the Indian Constitution, guarantees that every individual is equal before the law and has equal protection under it[511]. This fundamental right applies to various aspects of life, including healthcare and medical research. In the context of clinical trials, Article 14 ensures that no individual is unfairly excluded or exploited based on factors like socioeconomic status, gender, caste, or geographic location. It also emphasizes the importance of fair participant selection, non-discrimination, and equal access to the benefits of trials, including post-trial medical care.

6.1. *Discrimination in Participant Selection in Clinical Trials*

Clinical trials are essential for developing new drugs and medical treatments, but the process of selecting participants must be fair and unbiased. However, in some cases, discrimination occurs in ways that violate the Right to Equality.

a) *Exploitation of Vulnerable Populations*

One of the most concerning issues in clinical trials is the targeting of vulnerable populations, particularly poor and illiterate individuals, for drug testing. Many pharmaceutical companies prefer conducting trials in economically disadvantaged areas because individuals in these communities may not fully understand the risks and are more likely to participate due

[509] Swasthya Adhikar Manch v. Union of India, 14, SCC, 788, 791, 2014, there should be a robust system for conducting clinical trials in our country, 1st April, 2025, 1:45 PM

[510] Kalpana Mehta v. Union of India, 7, SCC, 1, 87, 2018, 1, licensing was not preceded to adequate clinical trials, 1st April, 2025, 2:25 PM

[511] Moulik, Right To Equality Article 14 to 18, Lawnote, 2024, https://lawnote.in/right-to-equality-article-14-to-18/>, 1st April, 2025, 2:50 PM

to financial incentives. This leads to an unfair burden of risk on specific groups, violating the principle of equality. The Swasthya Adhikar Manch v. Union of India (2013) case highlighted this issue, leading to stricter regulations to prevent the exploitation of vulnerable individuals.

b) *Gender Disparities in Clinical Trials*

Another major concern is the underrepresentation of women in clinical trials. Historically, many medical studies have focused more on male participants, leading to a lack of data on how treatments affect women differently. Women's bodies react differently to certain medications due to hormonal and genetic differences, yet they are often excluded from trials due to concerns about pregnancy-related risks. This gender bias in participant selection can lead to ineffective or unsafe treatments for women, violating their right to equal healthcare.

c) *Caste and Racial Bias in Medical Research*

In some cases, individuals from lower castes or marginalized communities face barriers to participation in clinical trials due to lack of awareness, mistrust in the medical system, or systemic discrimination. On the other hand, certain communities may be unfairly overrepresented in risky trials while being excluded from the benefits of medical advancements. Ensuring diversity and fair representation in clinical trials is essential to uphold Article 14.

6.2. *Equal Access to Trial Benefits and Post-Trial Medical Care*

While clinical trials help bring new medicines to the market, the benefits of these trials should be fairly distributed among all participants. However, inequality often persists in accessing trial benefits, especially regarding post-trial medical care.

a) *Limited Access to New Treatments*

Once a clinical trial is completed, the new drug or treatment is often made available only to those who can afford it. Many participants from lower-income backgrounds, who took on the risks of experimental treatment, may not have access to the final approved medicine due to high costs or lack of healthcare infrastructure. This creates a gap between those who participate in trials and those who benefit from them, violating the principles of equality and justice.

b) *The Issue of Post-Trial Care*

After a trial ends, participants who may have developed side effects or long-term health issues due to the experimental treatment often do not receive continued medical support. Ethical research guidelines, such as the World Medical Association's Declaration of Helsinki, emphasize the responsibility of researchers to provide post-trial care, but this is not always enforced. The Indian Supreme Court, in cases like Union of India v. Pfizer Ltd. (2022), has reinforced the need for compensation and continued medical assistance for those affected by clinical trials.

c) *The Role of Government and Pharmaceutical Companies*

To ensure equality in clinical trials, both the government and pharmaceutical companies must take steps to provide fair access to treatments and post-trial benefits. Some key measures include:

- Making successful trial drugs available at affordable prices to all participants.
- Ensuring that trial sponsors provide long-term medical care for those affected by the trial.
- Strengthening regulations to enforce fair and non-discriminatory participant selection.
- Raising awareness in rural and marginalized communities so that they can make informed decisions about participation.

The Right to Equality under Article 14 is crucial in ensuring that clinical trials are conducted fairly, ethically, and without discrimination. From participant selection to post-trial access to healthcare, all individuals must be treated

equally, regardless of their background. Past instances of exploitation, gender bias, and unequal access to treatments have highlighted the need for strong legal protections and ethical standards. The Indian Supreme Court has played a key role in reinforcing these rights, ensuring that scientific progress does not come at the cost of human dignity and justice. By enforcing strict regulations and prioritizing ethical research practices, India can uphold the Right to Equality while continuing to advance in medical research.

7. Conclusion

Clinical trials are a cornerstone of medical research, playing a vital role in the discovery and development of new drugs and treatments. They provide essential scientific evidence regarding the safety and efficacy of medicines before they are introduced to the public. In India, clinical trials have evolved significantly, shaped by historical developments, regulatory advancements, and legal safeguards that prioritize ethical considerations and participant welfare.

The Indian regulatory framework, governed by the CDSCO and DCGI, has strengthened over the years to ensure transparency, informed consent, and fair compensation for participants. The introduction of the Good Clinical Practice (GCP) guidelines, the New Drugs and Clinical Trials Rules of 2019, and Supreme Court rulings such as Swasthya Adhikar Manch v. Union of India (2013) have been instrumental in protecting the rights of individuals involved in research studies. These legal and ethical safeguards align with fundamental constitutional rights, particularly Article 21 (Right to Life and Health) and Article 14 (Right to Equality), ensuring that clinical research does not exploit vulnerable populations.

Despite these advancements, challenges persist. Ethical concerns, participant exploitation, and gender and socioeconomic disparities in clinical trial representation continue to raise important questions about the fair implementation of research protocols. Addressing these issues requires ongoing government intervention, stricter enforcement of ethical standards, and greater public awareness to ensure that participation in clinical trials is truly voluntary, informed, and equitable.

Moving forward, India must balance scientific progress with human rights by ensuring that clinical trials not only adhere to global ethical standards but also provide accessible benefits to all participants, regardless of their background. Strengthening post-trial access to successful treatments, increasing diversity in participant selection, and holding pharmaceutical companies accountable for fair compensation are crucial steps toward achieving a more just and ethical clinical trial ecosystem.

Ultimately, clinical trials must continue to be conducted with the highest ethical integrity, respecting the dignity and rights of participants while advancing medical research for the greater good.

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