



Review Article

Legal implications in clinical trials for cancer in India: A comprehensive analysis of regulatory and ethical challenges, navigating consent, compliance, and participant protection in oncology trials

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Abstract

Background: Clinical trials for cancer play a critical role in developing new therapies and enhancing patient care. However, there are particular ethical and legal issues with these trials, especially with regard to participant safety, regulatory compliance, and patient consent. The New Drugs and Clinical Trials Rules, 2019 in India offer a framework that prioritizes data transparency, participant rights, and ethical oversight. This article explores the intricate regulatory environment and emphasizes how crucial strong ethical standards are when performing oncology trials.

Aims and Objectives: This review aims to assess the ethical and legal aspects of cancer trials in India, with a specific focus on informed consent and compliance with the New Drugs and Clinical Trials Rules, 2019.

Materials and Methods: The Drugs and Cosmetics Act of 1940, the New Drugs and Clinical Trials Rules of 2019, and the Indian Council of Medical Research (ICMR) guidelines are among the pertinent Indian laws and regulations that are reviewed in this study. Judicial precedents were also examined to assess their impact on clinical trial practices, with additional insights drawn from secondary literature on patient consent, ethics, and challenges specific to oncology.

Conclusion: Future improvements should focus on harmonising national regulations with global standards and enhancing participant protections, especially in complex fields like oncology.

Keywords: Clinical trials, Cancer research, Legal implications, Informed consent, Regulatory compliance, India, Research ethics, Patient rights.

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1. Introduction

Cancer is a global health crisis, with the development of effective treatments relying heavily on rigorous clinical trials. These trials help ensure the safety, efficacy, and quality of new interventions, advancing oncology research and potentially offering life-saving options for patients.¹ In India, the clinical trial landscape has undergone significant regulatory transformation to enhance participant safety and ethical conduct, particularly through the New Drugs and Clinical Trials Rules, 2019.² This regulatory framework was introduced to address past challenges within India's clinical trial environment, including concerns over inadequate informed consent practices, insufficient participant protections, and inconsistent trial data transparency. These

regulations are pivotal in establishing protocols for the conduct of trials, ensuring ethical adherence, and mandating participant rights to autonomy and safety.

Oncology trials often involve high-risk, invasive treatments that may carry significant physical and psychological impacts on participants.³ Ensuring informed consent in such settings requires participants to understand the complex procedures, risks, and outcomes involved—a task further complicated in India by factors such as low health literacy, language barriers, and diverse cultural backgrounds. Judicial rulings have reinforced the need for comprehensive, voluntary, and specific informed consent, distinguishing it as a core component of ethical clinical trials.^{4,5}

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The introduction of the New Drugs and Clinical Trials Rules, 2019, represents a substantial step forward in standardizing trial procedures.^{6,7} These rules aim to protect participants while fostering a robust framework for advancing research.

Yet, ensuring that all participants fully comprehend informed consent can be challenging in India, where language diversity, varying education levels, and cultural factors influence how information is processed and understood. Further, resource constraints within some clinical trial facilities limit the extent to which trial administrators can educate participants and monitor compliance. As a result, questions remain about the adequacy of protections provided by the current regulatory framework and the measures needed to bridge gaps in ethical practices.⁸

2. Aims and Objectives

This review aims to assess the ethical and legal aspects of cancer trials in India, with a specific focus on informed consent and compliance with the New Drugs and Clinical Trials Rules, 2019.

3. Materials and Methods

The review draws on a comprehensive examination of Indian legal documents, including the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019, as well as ethical guidelines from the Indian Council of Medical Research (ICMR). Key judicial precedents on patient consent and clinical trial ethics, such as *Samira Kohli v. Dr. Prabha Manchanda*, are analysed for their impact on ethical practices. Supplementary sources include academic literature and case studies focused on oncology trial ethics, participant protections, and compliance issues, providing a foundation for identifying recommendations to enhance ethical standards in Indian oncology trials.

4. Informed Consent in Oncology Clinical Trials

Informed consent is foundational to ethical clinical trials, especially in oncology, where procedures can be invasive and carry substantial risks. Indian law requires that consent be specific, prior, and well-informed, detailing risks, benefits, and alternatives. Legal precedents clarify that consent for diagnostic interventions cannot be assumed for treatments unless explicitly specified, reinforcing patient autonomy.⁹

5. Regulatory Compliance and Legal Framework

The new drugs and clinical trials rules, 2019 offer a structured approach to clinical trials, mandating:¹⁰

1. Registration and approval: All trials must be registered and approved by the Drug Controller General of India (DCGI).
2. Ethics committee oversight: Trials require approval from institutional ethics committees, ensuring adherence to ethical standards.
3. Transparency and data access: Trial outcomes must be publicly accessible, fostering transparency and reducing bias.
4. Compensation for adverse events: Participants are entitled to compensation for injuries or adverse effects, promoting accountability.

6. The Ethical Challenges in Cancer Clinical Trials in India

Cancer clinical trials in India face substantial ethical challenges, particularly in obtaining informed consent, ensuring participant safety, and maintaining transparency. These trials often involve invasive procedures and high-risk treatments, making it essential for participants to understand potential risks. However, language barriers, cultural diversity, and low health literacy complicate this process, sometimes leading to consent that lacks true comprehension. Ethical issues also arise in managing participants' expectations, as patients might mistakenly believe experimental treatments are guaranteed to be effective. Additionally, transparency in reporting trial outcomes is crucial but not consistently achieved, affecting public trust and accountability. Ensuring that adverse events and all trial data are disclosed can be resource-intensive, particularly in underfunded settings. Lastly, equitable access to compensation for harm remains a concern, as trials must address causality challenges, especially with pre-existing health conditions. Addressing these ethical challenges is crucial for aligning Indian clinical trials with global standards and fostering an ethically sound research environment.

7. Ensuring Ethical Conduct in Cancer Trials: Legal Frameworks and Participant Rights (Figure 1)

The correlation between cancer clinical trials and legal implications is profound, as these trials operate at the intersection of innovative scientific research, patient care, and regulatory compliance. Cancer clinical trials, which aim to explore new therapies, drugs, or treatment regimens, inherently involve significant risks due to the nature of cancer and its treatments. Therefore, regulatory frameworks and legal provisions are crucial to protect participants' rights and welfare. Here, we will examine how legal implications shape the conduct, ethical considerations, and outcomes of cancer clinical trials in India, drawing insights from the uploaded articles on legal frameworks, clinical trial regulations, and informed consent in cancer care.

Regulatory Compliance

- Approval by Drug Controller General of India (DCGI)
- Ethics Committee Oversight
- Good Clinical Practice (GCP) Guidelines
- Post-trial obligations (e.g., compensation for adverse events)

Informed Consent

- Specific, voluntary, and comprehensive consent
- Requirement for separate consent at each trial stage
- Judicial precedents (e.g., *Samira Kohli v. Dr. Prabha Manchanda*)
- Addressing literacy, language, and cultural barriers

Data Transparency and Reporting

- Public availability of trial results
- Disclosure of both positive and negative findings
- Compliance with International Committee of Medical Journal Editors (ICMJE) standards
- Balance between transparency and patient confidentiality

Participant Safety and Liability

- Compensation for injuries or adverse events
- Determination of causality in adverse events
- Ethical responsibility of sponsors and investigators
- Legal protections for participants in high-risk cancer trials

Judicial Influence on Ethical Standards

- Reinforcement of patient autonomy and informed consent
- Distinction between therapeutic and non-therapeutic interventions
- Case law establishing ethical guidelines for trials

Role of judiciary in safeguarding participant rights

- **Challenges in Practical Implementation**
- Ensuring ethical standards across diverse settings
- Addressing therapeutic misconception
- Impact of resource constraints on compliance
- Navigating cultural influences on consent and decision-making

Figure 1: Legal implications in cancer clinical trials

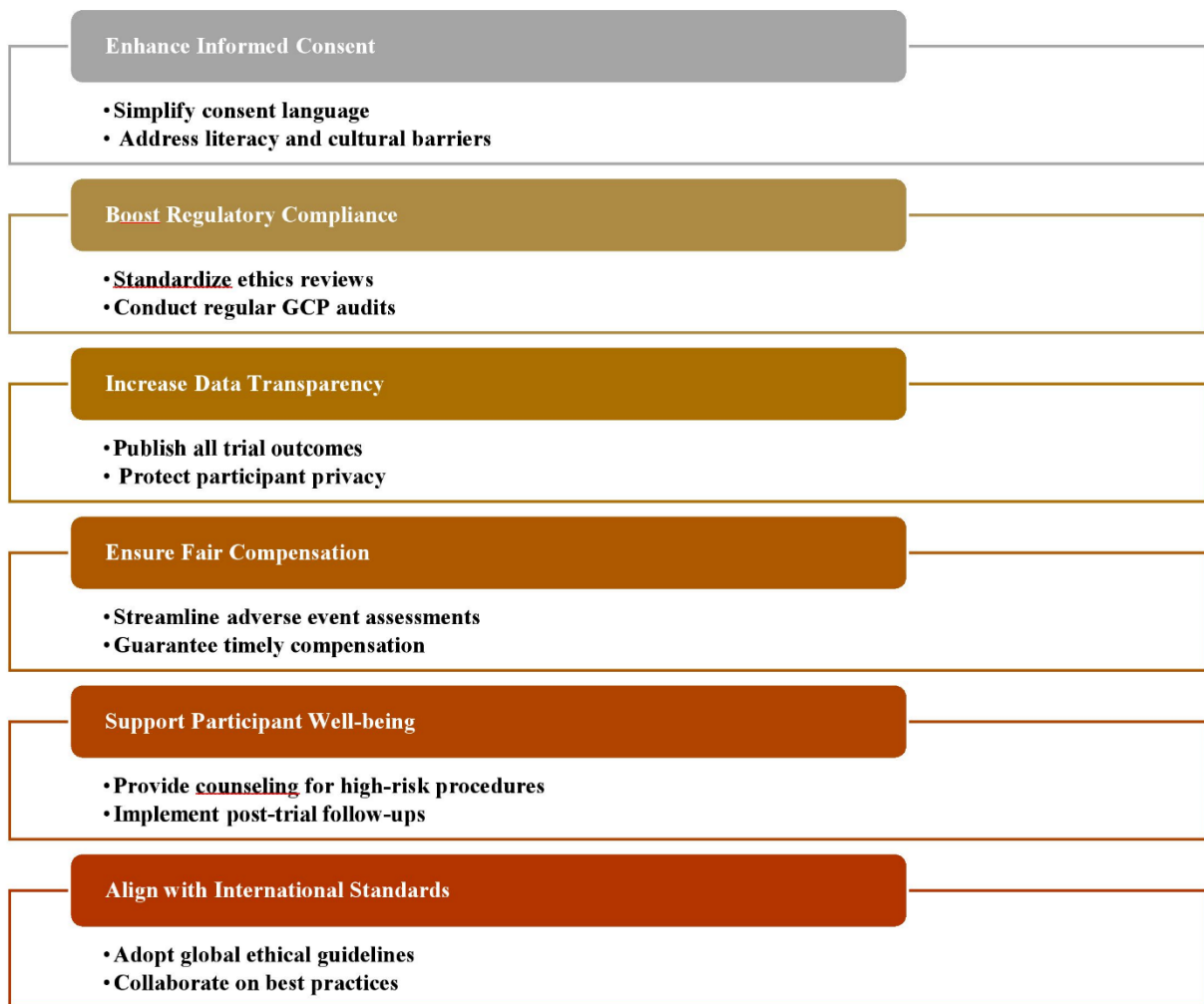


Figure 2: Recommendations for enhancing legal and ethical standards in cancer clinical trials

7.1. Regulatory compliance and ethical standards

Cancer clinical trials are strictly regulated to ensure that participant safety, ethical standards, and scientific validity are maintained throughout the study. In India, the New Drugs and Clinical Trials Rules, 2019 provide a comprehensive legal framework governing clinical trials, including those for cancer. These rules mandate that all clinical trials must be approved by the Drug Controller General of India (DCGI) and overseen by institutional ethics committees.¹¹ This oversight ensures that trials adhere to protocols that protect patient rights and safety, requiring that sponsors and investigators follow strict ethical guidelines, especially in areas of informed consent and participant autonomy.

Ethics committees play a significant role in reviewing trial designs, including the risk-to-benefit ratio and the adequacy of participant protections. For cancer clinical trials, where treatments are often experimental and carry high risks, ethical scrutiny is even more critical. The law requires that all clinical trials follow Good Clinical Practice (GCP) guidelines, which are a set of internationally recognised ethical and scientific quality standards that regulate trials involving human subjects. The New Drugs and

Clinical Trials Rules also make provisions for post-trial obligations, such as compensation for adverse events or injuries, further demonstrating the legal system's role in ensuring that participants' well-being is prioritised.

7.2. Informed consent and patient autonomy

Informed consent is a foundational aspect of legal compliance in cancer clinical trials, serving as both an ethical and legal requirement. Cancer treatments can involve invasive procedures, significant side effects, and potentially life-threatening risks, making it essential that participants understand the implications of their involvement. Legal standards in India, as reinforced by judicial precedents, require that informed consent be specific, comprehensive, and voluntarily obtained. The 2019 rules emphasise that participants must be fully informed about the risks, benefits, and alternatives to the treatment being studied. For instance, the case of *Samira Kohli v. Dr Prabha Manchanda* clarified that consent for a diagnostic procedure does not extend to therapeutic interventions without explicit patient approval, reinforcing the legal distinction between distinct phases of treatment consent.¹²

Cancer trials may involve multiple stages, such as diagnostic tests, therapeutic interventions, and follow-up care. Indian courts have mandated that consent must be obtained at each stage, especially when treatments escalate in invasiveness or risk. This legal requirement ensures that participants have control over their involvement at every phase, safeguarding their autonomy and allowing them to make informed decisions based on their understanding of the potential risks and benefits. Additionally, the consent process must be documented in writing, particularly for high-risk procedures, and trial administrators are legally obliged to provide information in an understandable format, addressing language and literacy barriers where necessary.

7.3. Data transparency and reporting obligations

Transparency in data reporting is a legal requirement that has significant implications for cancer clinical trials. The 2019 rules mandate that trial results must be made publicly available, which includes the publication of adverse effects, efficacy data, and other relevant outcomes. This transparency serves several purposes: it enhances public trust in clinical research, enables other researchers to benefit from the findings, and ensures that negative results or adverse effects are not hidden from potential participants or healthcare providers.

In the context of cancer clinical trials, transparency is essential due to the severity of the disease and the need for accurate data to guide treatment decisions. Legal obligations for data transparency also align with international ethical standards, such as the International Committee of Medical Journal Editors (ICMJE), which requires that clinical trials be registered, and results reported publicly. However, compliance with these requirements remains challenging, as many trials do not fully report adverse effects or may selectively publish favourable results, potentially skewing public perception. The legal implications of non-compliance are significant, as they can lead to penalties, disqualification from future research funding, or damage to an institution's reputation.¹³

7.4. Compensation and liability for adverse events

One of the core legal implications of cancer clinical trials is the liability of sponsors and investigators for adverse events experienced by participants. Due to the experimental nature of cancer treatments, trials often involve considerable risks, and adverse effects may range from minor complications to life-threatening conditions. The New Drugs and Clinical Trials Rules, 2019, legally mandate that trial sponsors provide compensation for injuries or fatalities related to the trial. This provision addresses the ethical obligation to protect participants from financial burdens resulting from their involvement in the research.

The rules stipulate that compensation should be provided promptly and must cover all necessary medical expenses, in addition to any further compensation calculated based on the

severity of harm. The legal liability extends to both Indian and international sponsors conducting trials in India, which ensures that participants are protected regardless of the trial's origin. However, calculating compensation and proving causality can be complex, as adverse events may be influenced by underlying health conditions or other variables not related to the trial. The legal framework, therefore, also outlines procedures for investigating adverse events to determine responsibility and appropriate compensation.

7.5. Judicial precedents shaping legal obligations in cancer trials

Indian judiciary has played a proactive role in reinforcing the rights of clinical trial participants, particularly through landmark judgments that clarify legal standards. Cases like *Samira Kohli v. Dr Prabha Manchanda* have underscored the necessity for specific, informed consent at each stage of treatment, a principle that is especially relevant for oncology trials where procedures can be progressively invasive. Judicial interventions have helped shape the legal landscape by holding medical practitioners and researchers accountable to high ethical standards, ensuring that patient welfare remains central to clinical research.

Moreover, the judiciary has highlighted the importance of distinguishing between therapeutic and non-therapeutic research. In cancer clinical trials, this distinction is crucial, as participants may be misled to believe that trial treatments are a form of medical care rather than experimental interventions. Legal judgments have reinforced that participants must be informed if they are part of a control group receiving standard care or a placebo, ensuring that their expectations align with the trial's reality. These rulings aim to minimise therapeutic misconception, where participants believe they are receiving proven treatments rather than experimental therapies, thereby enhancing transparency and trust in clinical research.

7.6. Balancing innovation with legal compliance

The regulatory and legal requirements in cancer clinical trials are essential to protect participants, but they also present challenges to the advancement of research. Balancing participant protection with the need for scientific innovation is complex, as overly stringent legal requirements can delay trial approvals or limit the scope of research. For example, obtaining informed consent in a manner that fully adheres to legal standards can be resource-intensive, particularly when considering India's diverse linguistic and cultural landscape. Additionally, compliance with transparency and data-sharing obligations requires substantial infrastructure and resources, which may be a challenge for smaller institutions.

However, while these regulations can be perceived as constraints, they serve to enhance the credibility and ethical foundation of cancer clinical trials. Legal compliance ensures that research is conducted responsibly and that the rights of participants are respected, which can improve public perception and willingness to participate in future trials. By

adhering to these legal standards, cancer researchers in India contribute to a more ethically robust and scientifically valid field, benefiting both current and future patients.

8. Discussion

The legal framework for cancer clinical trials in India balances scientific progress and participant rights, which is crucial in high-risk oncology trials. These trials face ethical challenges, particularly regarding informed consent, regulatory compliance, data transparency, and practical implementation issues. Informed consent remains a cornerstone of ethical clinical research in India, especially in oncology, where invasive treatments demand thorough participant understanding. Indian legal standards, reinforced by judicial rulings, mandate consent to be specific and voluntary to ensure participant autonomy.^{4,5} However, the diverse linguistic and cultural landscape in India often complicates this process, as patients may face language barriers, and family members may influence decision-making.

The New Drugs and Clinical Trials Rules, 2019, represent an advancement in establishing ethical standards by requiring approval from the Drug Controller General of India (DCGI) and ethics committees to ensure scientific and ethical validity. Adherence to Good Clinical Practice (GCP) guidelines further emphasizes accountability, though meeting these requirements can be challenging for smaller institutions with limited resources, potentially delaying research progress.^{6,7} Another essential aspect is data transparency, legally mandated to build public trust and align with international standards, such as the ICMJE guidelines.¹⁴ However, some sponsors may still selectively disclose positive results, which undermines transparency and public confidence. The legal requirement for transparency also intersects with privacy concerns, as sensitive genetic and medical information in oncology trials must be safeguarded.

In practice, translating these ethical standards into action is challenging in India's diverse and resource-limited settings. Many cancer patients view trials as assured treatments, leading to therapeutic misconceptions, which trial administrators must clarify through effective communication. Additionally, the socio-cultural diversity in India influences consent dynamics, with some communities involving family in decision-making, which requires cultural sensitivity to maintain genuine, informed consent.

The judiciary in India has reinforced ethical standards in clinical trials through landmark cases such as *Samira Kohli v. Dr. Prabha Manchanda*, upholding the necessity of informed consent at each trial stage, particularly in high-risk fields like oncology.^{4,5} These rulings highlight the judiciary's role in maintaining transparency and patient autonomy, aligning Indian ethical standards with global norms and acting as a safeguard against unethical practices.

While the Indian regulatory framework prioritises participant protection, balancing these legal requirements with the need for timely research progression remains a challenge. Developing flexible policies, investing in resources for compliance, and promoting cultural sensitivity in communication can enhance trial quality and support innovation in a way that respects and protects trial participants.

9. Conclusion

India's regulatory landscape for clinical trials has significantly advanced, with the 2019 rules providing a comprehensive framework for ethical conduct, participant protection, and data transparency. However, ongoing challenges such as achieving informed consent and ensuring compliance across diverse populations highlight the need for continuous improvements. Harmonising Indian regulations with global standards, enhancing training for trial administrators, and investing in resources for participant education are crucial next steps in ensuring ethical and legally compliant clinical trials in oncology.

10. Source of Funding

None.

11. Conflict of Interest

None.

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