Central University of Karnataka
Journal of Legal Studies
Volume 1 Issue I (2025)

Striking a Balance: A Human Rights Perspective on Informed Consent in Clinical Trials in India

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Category:
Research Paper

Paper Code:
CUKJLS2504

Accepted on:
September 12, 2025

Abstract
In recent times, India has become a major site for clinical trials. The country's vast and diverse population provides unique opportunities for medical innovation. While these trials offer possibilities for medical progress, they also raise serious ethical concerns surrounding informed consent, protection of vulnerable populations, transparency, and fair compensation. Informed consent, which ensures that subjects are aware of the risks, benefits, and alternatives before consenting to participate in clinical studies, is an essential aspect of ethical medical research. Yet in India, where socio-economic disparities, cultural norms, and literacy levels vary widely, obtaining truly informed consent presents unique challenges. This article explores how informed consent, when not carefully taken, can become a mere formality rather than a meaningful ethical commitment, especially for vulnerable populations. It argues that informed consent must be deep-rooted in the human rights principles of autonomy and dignity. In an attempt to achieve an equilibrium between informed consent and human rights principles, this article critically evaluates regulatory frameworks, international ethical guidelines, and judicial developments, highlighting the essence of patient autonomy and the dignity of the research participants, which are vital for the effective conduct of clinical trials. In doing so, the article suggests a rights-based, context-sensitive approach to informed consent that addresses India's diverse socio-cultural landscape and proposes a reform-oriented consent model.

Keywords: Clinical Trial; Informed Consent; Autonomy; Human Rights; Equilibrium; Regulations.

Introduction

The right to health is deeply connected with the availability of safe and essential medicines (UDHR, Article 25). Clinical trials are crucial in ensuring the efficacy and safety of new drugs before they reach the general public. Such trials are a type of research that evaluates new tests and treatments, assessing their effects on human health outcomes. People volunteer to participate in clinical trials to test medical interventions, including drugs, cells, and other biological products; surgical procedures; radiological procedures; devices; behavioral treatments; and preventive care (WHO, Clinical Trials).

With the global expansion of biomedical research, India has become a favorable destination to conduct clinical trials because of a larger pool of participants from diverse populations, a large range of diseases to be tested and treated, well-qualified medical providers, affordable healthcare facilities, a sound infrastructure for medicine, and a relaxed regulatory system (Vennu and Saini 2020, p.726). The World Health Organization ranks India as the third-largest pharmaceutical market in the world, having grown at an annual rate of over 10 percent since the last decade (Desai and Shah 2004, p. 180). Clinical trials, which typically progress through structured phases from small-scale studies involving volunteers to large-scale trials involving patients, play a crucial role in today's biomedical market.(Desai,2022). However, as the number of clinical trials has increased, emphasis must also be given to the rights and safety of human volunteers (Evangeline et al., 2017, p. 165).

These trials raise several complex ethical questions, including *informed consent, the estimation of potential benefits and harm, the selection of human participants, prejudice and truth-telling, confidentiality, respect for human dignity, and respect for fairness* (Constantin 2018, p. 137). An essential ethical commitment is the 'principle of informed consent,' which ensures that participants in the study are well aware of the benefits and risks of the study (Garg et al. 2012, p.1). This principle, which stands at the heart of ethical commitment, is grounded in the 'principles of autonomy, self-determination, and dignity.'

In India, socio-economic disparities, literacy gaps, and power imbalances between researchers and

participants stand as a challenge in obtaining valid and meaningful consent. As global and international frameworks are increasingly focusing on participant safety and protection, the Indian regulatory framework, too, requires a critical examination of whether consent acquired from participants is true, informed, and voluntary. In light of this, the article explores the intersection between informed consent and human rights principles in Indian clinical trials. Through a careful examination of international ethical principles, guidelines, national policies, and regulatory frameworks, this article advocates for a patient-centered and rights-based approach that upholds autonomy and dignity on the one hand, and ensures that participants are not exploited in the name of scientific progress and medical need on the other. By critically evaluating India's ethical and legal landscape, this article finally aims to lay down certain recommendations to enhance informed consent practices and at the same time, strengthen human rights protections of research participants in India.

Informed Consent in Clinical Trials

In legal parlance, consent is said to be given when 'two or more people agree on the same matter in the same sense.' Consent must be free and voluntary, and cannot be influenced by coercion, undue persuasion, fraud, misrepresentation, or error (The Indian Contract Act, 1872). In regard to medical research, consent is a necessity. However, simply signing the consent form does not amount to genuine informed consent until it is accompanied by an adequate understanding of the proposed intervention (Ajay et al. 2015, p. 695). This concept, when ethically practiced, is a reciprocal process built on key elements: *threshold elements* including voluntarism and competence (Roberts 2002,p. 605), *information elements,* which involve providing participants with thorough information on the study, its methods, dangers, rewards, and their privileges as research subjects; the *counselling* element including consent and dialogue; and the *relationship elements,* which require participants to be treated with respect and dignity, acknowledging the social and relational contexts that influence their decisions. These elements align with core ethical *principles of autonomy, beneficence, justice, transparency, and accountability*.' Autonomy states the right of every individual to retain control over decisions affecting their bodies. Beneficence and non-maleficence ensure that research involving human participants must minimize harm while maximizing benefits. Justice ensures a fair selection of participants, irrespective of the risks or benefits. Transparency requires full disclosure of the ongoing study, while accountability ensures that researchers are held responsible for safeguarding participants' safety and welfare (Varkey 2020, p. 19).

Internationally, the concept of informed consent gained recognition after the atrocities committed during Nazi medical experiments, which resulted in the formulation of the Nuremberg Code, 1947. Principle 1 affirms "the voluntary consent of the human subject is essential," thereby establishing that every human experimentation must be accompanied by a degree of voluntariness and the participant's willingness to engage in research studies (Kovane, Nikodem, and Oswell 2022, p. 48). Principle 2 of the Code further states "the experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature" (The Nuremberg Code). The Belmont Report (1979) further advanced three key ethical principles: '*respect of persons* (*autonomy*), *beneficence,* and *justice*' (The Belmont Report). Apart from international frameworks, judicial recognition of informed consent has also shaped its ethical foundation. In the judgment of *Schloendorff v. Society of New York Hospital* (1914), Lord Benjamin Cardozo pointed out, "*Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who operates without his patient's consent commits an assault for which he is liable in damages.*" Subsequent judgments, such as the *California Salgo trial* (1957), *Montgomery v. Lanarkshire Health Board* (2015), and *Canterbury v. Spence* (1972), emphasized that the ethical obligation of informed consent involves not only voluntary agreement on the part of participants but also adequate disclosure of risks, benefits, alternatives, and consequences of the study, thereby upholding a patient's right to make reasoned healthcare decisions.

In the context of India, the 'principle of informed consent' finds constitutional grounding in 'Article 21 of the Constitution of India,' which protects 'the right to life and personal liberty' (Nandimath 2009, p. 345). The Indian judiciary has, time and again, interpreted this article to include bodily integrity, the right to privacy, and the freedom to make autonomous decisions as to one's body. The Supreme Court of India, in the *Jacob Puliyel v. Union of India* case (2021), asserted that Article 21 of the Constitution of India safeguards the integrity of the body and that no one can be forced

to undergo immunization. (para 41). Further, 'Article 19(1)(a) of the Constitution of India ensures that every citizen of India has the 'right to freedom of speech and expression.' As part of this fundamental right, each subject has the right to receive adequate details about the nature of research and the hazards involved in taking part in it (Goyal 2023, p. 1). In this regard, *Samira Kohli v. Dr. Prabha Manchanda & Another* (2008), is a notable case addressing the significance of informed consent for medical care in India. The court determined that the appellant's failure to give consent for a particular surgery amounted to an unauthorized invasion and interference with her body, resulting in a torturous act of assault and battery, and as such, medical service was deficient (Himani 2020, p.256).

The importance of informed consent is further highlighted by India's past trial controversies, such as the oral cancer trials (1999) and HPV vaccine trials (2009), which revealed serious failures in obtaining valid consent from the participants involved. Following public uproar and several litigations, the Supreme Court, in *Common Cause v. Union of India* (2005), instructed the Indian government to establish an autonomous entity that would supervise clinical trials and also ensure that they were carried out safely, adhering to all pertinent domestic laws and regulations. Further, in the cases of *Rahul Dutta v. Union of India* (2010) and *Swasthya Adhikar Manch v. Union of India* (2012), the Supreme Court thoroughly criticized the Indian government for its inability to stop illegal clinical trials from taking place in the nation.

The principle of informed consent, thus, must not be viewed only as a legal need but also as a human rights need. International instruments, such as the Universal Declaration of Human Rights,1948, and the International Covenant on Civil and Political Rights, 1966, acknowledge one's 'right to existence and freedom from every inhumane torture' as inherent human rights. India has made significant strides in recognizing informed consent as a vital necessity, but challenges still persist, particularly in how consent is given in India, where family decisions, societal obligations, and cultural expectations often influence health decisions. In this regard, relational autonomy challenges the Western notion of individual autonomy, as individuals rarely make decisions in isolation; rather, their choices are highly influenced by the complex social structures (Virseda, Maeseneer, and Gastmans 2019, p.8). Thus, in a country like India, expecting participants to make autonomous decisions often clashes with the lived realities. It was seen during the HPV vaccine trials in Andhra Pradesh and Gujarat (2009), where several tribal girls were selected for participation in the study without their guardians fully being informed about the risks involved. Investigations revealed that many forms were thumb-printed without proper explanation, while others were not aware that they were part of the experimental study (Sarojini and Shenoi 2010). Such unethical trials underline the need that India must embrace a dynamic, context-sensitive consent model that respects not only individuals' decision-making capacity but also the broader socio-cultural settings in which such decisions are given. Another concern is that in the present times, in many multi-site clinical trials, consent is often reduced to a check-box activity, thereby lacking in meaningful dialogue between researchers and participants, especially when conducted in regions with low literacy and limited health access. India, too, remains vulnerable to such practices. Such a form of 'tokenistic consent' has negative consequences (Childress, Nayyar, and Gibson 2024, p.31), as it undermines the 'principle of autonomy and self-determination and creates power imbalances between the parties involved in the research activity.'

Balancing Informed Consent in Clinical Trials and Human Rights Principles

Human rights are commonly recognized principles that safeguard the dignity, freedom, and well-being of every individual. In India, the Protection of Human Rights Act of 1993 defines 'human rights' as 'the rights relating to life, liberty, equality, and dignity of the individual guaranteed by the Constitution or embodied in the International Covenants and enforceable by courts in India'. In the context of human experimentation, these rights include the right to be informed, to make voluntary decisions, and to be treated with respect, confidentiality, and fairness.

As mentioned earlier, the foundational ethical codes, such as the Nuremberg Code, the Helsinki Declaration, the Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects, all emphasize voluntary, informed participation as a non-negotiable process to be followed. The Human Rights Committee General Comment No. 20 (1992) of the ICCPR further states that no trial subject should be in any form of confinement or captivation, and parties to the committee of ICCPR shall furnish appropriate information that

would form the basis of the legitimate consent for every research subject. The 1949 Geneva Convention and the 1977 Additional Protocols on International Humanitarian Law prohibit human experiments *sans* informed consent and knowledge of the patients. Similarly, the Universal Declaration on Bioethics and Human Rights, 2005, mandates respect for dignity, autonomy, and transparency in all medical interventions. All these international instruments highlight the fact that it becomes vital to strike an equilibrium between informed consent and human rights. Informed consent upholds patients' right to self-determination and prevents them from being taken advantage of. In *Airedale National Health Service Trust v Bland* (1993), the court, emphasizing the 'principle of self-determination,' held that the desires of every patient undergoing any treatment must be respected, thereby reaffirming individuals 'right to autonomy over their own bodies.' (Butler-Sloss LJ.)

Consequently, to guarantee the preservation of human rights in clinical studies, it is crucial to present research information in a clear, understandable, and comprehensible manner that encourages voluntary participation (Mats 1998, p.182). This is essentially important for the vulnerable populations, whose voluntary consent might be influenced by the surrounding social, economic, or societal pressures. Vulnerable subjects are defined by ICH GCP Guideline E6 and include "*patients with incurable diseases, persons in nursing homes, unemployed or impoverished people, and patients in emergencies, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent*." Further, the United States Department of Health and Human Services (HHS) Policy for Protection of Human Subjects and CIOMS Guidelines stress the need for incorporating additional safeguards for this vulnerable class (Gordon 2020, p.34). The Declaration of Helsinki further points out that clinical investigation involving those with vulnerabilities is permissible only when the research conducted addresses the priorities or medical demands of that group (Helsinki Declaration, Principle 20).

In India, a nation marked by its cultural diversity, achieving equilibrium is not a legal necessity but a profound ethical responsibility. Members of particular socio-economically disadvantaged groups, such as children, the elderly, disabled persons, women, individuals suffering from HIV/AIDS, poor migrants, persons from Scheduled Castes (SC), Scheduled Tribes (ST), and sexually marginalized groups often face discrimination, including their access to health care (Yelgar, Kasarla, and Mujeebuddin 2020, p.1). It is to be noted that vulnerable populations should not be encouraged to participate in the research study if the risks involved in their participation are greater than minimal, the research conducted is not relevant to their class, or the procedure or intervention does not lead to any prospective benefits to individual subjects. The onus is on the investigators to justify their inclusion in the study that was conducted. They should ensure that the populations included in the research study are not exploited to generate clinical data, and if their inclusion exceeds minimal risk, it is to be justified, and additional safeguards are to be employed (Sanmukhani and Tripathi 2011, p.125).

In medical research backed by ethics, preserving patients' privacy and their well-being is quite important. Patients have the inalienable right to take part in clinical research voluntarily, without being subjected to undue pressure or influence, and the right to refuse participation at any point in time. The process of consent and consent forms should be determined by the standard of the population. Investigators should try incorporating simple language consent forms and provide additional educational facilities, well-qualified translators, and other relevant materials for a safe and ethical research study (See Gordon, p.36). Rigorous safety measures must be introduced to minimize risks and respond promptly to any adverse events. It is also required that all persons in the research study undergo basic training programs concerning counselling and preventive strategies, and the results need to be shared with all the persons involved in the study. For a country like India, balancing informed consent with human rights should be treated as a moral imperative grounded in the values of dignity, justice, and respect for life.

Regulatory Landscape of Clinical Trials in India

Clinical trial regulations in India reflect a commitment to participant security, scientific credibility, and ethical conduct. The Central Drugs Standard Control Organisation (hereinafter, CDSCO), operating under the Ministry of Health and Family Welfare, serves as the 'national regulatory authority,' entrusted with the duty of overseeing trial approvals, site inspections, and overall compliance. The Drugs Controller General of India (hereinafter, DCGI), as the head of CDSCO, is empowered to authorize

and evaluate clinical trials conducted nationwide, especially under the new 2019 rules (Gogtay, Renu, and Thatte 2017, p.192).

Complementing regulatory oversight is the Indian Council of Medical Research (hereinafter, ICMR), the supreme authority in India for the development, management, and encouragement of research in biomedicine. As the highest authority, it acts as a major player in the 'regulation, supervision, and promotion of clinical trials in India.' The central aim of ICMR is to promote research innovations in the thrust areas of medical care, treatment, and preventive immunizations while focusing more attention on research on health issues affecting the weaker, disadvantaged, and underrepresented segments of society. Through its network of Institutional Ethics Committees (IECs), the ICMR is in charge of regulating the ethical examination of clinical research protocols. It also has a significant role in building capacity and enhancing the capabilities of researchers, investigators, ethical committee members, and regulatory authorities involved in clinical research.

In 1980, the Policy Statement on Ethical Considerations Involved in Research on Human Subjects was released by the Indian Council of Medical Research. However, rapid advancements in biomedical research and technology have given rise to new ethical considerations, necessitating a further revision of these standards. Subsequently, in 2000, the Ethical Guidelines for Biomedical Research on Human Subjects and, in 2006, the Ethical Guidelines for Biomedical Research on Human Participants were published. In 2017, the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants were further updated, which now act as a comprehensive framework guiding clinical studies in India. These rules are intended to respect ethical standards and safeguard the basic rights of the participants involved. The ICMR further created the National Ethical Guidelines for Biomedical Research Involving Children, 2017, which offer comprehensive rules about the particular ethics to be followed in human experimentation involving children. In 2001, India framed the Good Clinical Practice guidelines in compliance with global mandates (Castelino et al. 2018, p.3209).

The statutory legislations for regulating clinical trials are underpinned by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945. Rules 122DA, 122DAA, 122DAB, 122DAC, 122DD, and 122E of the Drugs and Cosmetics Rules, 1945, and Schedule Y to the Rules prescribe guidelines relating to clinical research. Schedule Y has been amended several times to conform to international regulations. A notable amendment to Schedule Y introduced Rule 122DAB (2013), mandating compensation mechanisms for trial-related injury or death. Time and again, many notifications were issued, some of which tried to put into action the proposals laid down in the Ranjit Roy Chaudhury report (Ghooi 2014, p.100), as well as to show the country's concern towards past unethical trials and reflect a paradigm shift towards participant-centric regulation. To further bring another regulatory shift in the realm of clinical studies conducted in India, the New Drugs and Clinical Trial Rules, 2019, were introduced on March 25, 2019, to change the regulatory landscape encompassing the authorization of new drugs and the operation, efficacy, and proficiency of clinical research in the nation as a whole. The rules also resulted in the addition of 122DAA to the Drugs and Cosmetics Rules, 1945, which stated that Part XA and Schedule Y would be superseded by the new rules of 2019 with immediate effect (Annapurna and Rao 2020, p.279). The 2019 rules introduced simplified timelines for trial approval, mandatory registration of ethics committees, stringent monitoring mechanisms, post-approval surveillance, and clarity on compensation and reporting obligations (Singh et al. 2020). This reflects an awareness of the dynamic nature of clinical research and the need for adaptive regulatory measures to address emerging challenges. Further, to upsurge the accessibility and efficiency of filing online applications for clinical trials, the CDSCO introduced the 'SUGAM' portal. The Clinical Trial Registry of India (hereinafter, CTRI) is a publicly accessible, free online portal where investigator-initiated and regulatory studies need to register themselves. Clinical trial registration using the CTRI site has been made compulsory since June 2009 (Gogtay, p. 195). As of January 2024, 61,034 clinical studies across the nation were registered with CTRI.

Despite the progress made in regulatory reforms, the clinical trial landscape in India continues to face numerous hurdles. Ensuring the integrity of clinical trials and preserving participant rights remains a priority, particularly in the context of vulnerable populations and informed consent. Through the regulatory framework, responsibility has been cast upon the Ethics Committees for protecting the vulnerable class. However, the burden often falls on the researchers to justify inclusion and ensure equitable treatment, a task

that seems to be complicated by the limited monitoring infrastructure. Another constant concern is the imbalance of power in the researcher-participant relationship. Participants may perceive the giving of consent as an obligation, thereby failing to differentiate between research and treatment. The 2019 Rules address this by directing better consent practices and monitoring, but without strict enforcement, protections remain doubtful. India's rapid expansion as a favorable clinical trial destination, driven by its diverse population and low-cost healthcare infrastructure, thus demands continuous ethical care. Many clinical trials recruitment nowadays is done using e-consent platforms and app-based recruitment (Almeida et al. 2022). While these systems offer potential benefits, challenges may lie with regard to 'participant comprehension' and 'informed consent signature' (Mazzochi, Dennis and Chun 2023).

A brief comparison with South Africa highlights the role of community management, particularly when studies involve vulnerable groups (South African Department of Health 2015). Through the use of Community Advisory Boards and consultation practices, South Africa incorporates local voices into the trial design of clinical trials (Taylor 2013, p.96; Sleem et al. 2010, p.85). Adopting elements of community representation, consultation, and ethics training at the ground level could help India move towards a relational and patient-centered model in the future.

Conclusion

Like many other developing nations, India, too, carries a heavy burden of healing both infectious and non-communicable diseases. Clinical trials offer a vital avenue for discovering new treatments and improving health outcomes. With her diverse population, genetic variations, and growing health infrastructure, India has emerged as a valuable site for clinical research. India also collaborates with various international pharmaceutical companies and research organizations, thereby strengthening its position in the global research market on the one hand, and on the other, supporting the national economy through innovation, investment, and job creation. However, these benefits cannot come at the cost of ethics and the violation of human rights. It is, therefore, highly imperative that these trials adhere to fundamental human rights principles, as it is important to preserve trust in the medical research community and safeguard the dignity of individuals involved. India's clinical trial regulations, including guidelines set forth by the Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organization (CDSCO), act as a cornerstone for upholding ethical standards and safeguarding human rights in research. However, challenges persist, ranging from linguistic and cultural barriers to issues of autonomy and vulnerability among certain population groups.

To address these concerns, the following suggestions are imperative: First, the informed consent procedures need to be enhanced, ensuring that participants are given information that is clear, intelligible, and culturally appropriate, and no technical terms are used. The importance of ongoing consent throughout the trial, enabling participants to revoke consent at any moment, and providing regular updates on the study's progress needs emphasis. Second, the functions of Institutional Ethics Committees (IECs) in reviewing and monitoring clinical trials to ensure obedience with ethical principles and human rights values need to be strengthened. Third, it is necessary to conduct community outreach and educational programs to raise awareness about clinical research, informed consent, and human rights, empowering individuals to make informed decisions about participation. Finally, stringent regulatory standards are required relating to the process of conducting clinical trials, including informed consent requirements, participant protections, and reporting obligations. Such guidelines need to endorse transparency and accountability in clinical trial conduct by requiring public registration of trials, dissemination of trial results, and adherence to international reporting standards.

Striking a balance between scientific advancements and human rights principles is delicate, yet essential. As India strongly emerges as a global hub for medical research, it must also position itself as a role model for ethical responsibility and a global leader in participant-centered clinical research. As we evolve in the journey of clinical trial governance, we must ensure that our legal structures are not only legally sound but also ethically grounded.

By reinforcing transparency and accountability, strengthening consent mechanisms, and creating a rights-based, context-sensitive approach that safeguards the participants, stakeholders can collectively contribute to a healthy clinical trial landscape in India where informed consent becomes a true embodiment of individual autonomy and respect.

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