

INFORMED CONSENT AND CLINICAL TRIALS IN INDIA: REGULATIONS, CHALLENGES, AND THE PATH FORWARD

By

Sridhar Babu R

Research Scholar

School of Law

Ramaiah University of Applied Science,

Bengaluru

ABSTRACT

Exploring the intricate balance between regulatory frameworks and ethical considerations, the landscape of clinical trials in India has undergone significant evolution, particularly with the implementation of the New Drugs and Clinical Trials (NDCT) Rules, 2019. Central to this examination is the principle of informed consent, a pivotal aspect that ensures participants enter research willingly and with full awareness of their involvement. Historical perspectives provide a foundation, tracing regulatory milestones from the Drugs and Cosmetics Act of 1940 to the transformative NDCT Rules, 2019, marking India's commitment to align with international ethical standards while addressing its unique socio-economic challenges.

The NDCT Rules, 2019, herald a new era in clinical trial governance, emphasizing participant safety, ethical conduct, and scientific integrity. Despite these advancements, the practical application of these rules reveals gaps that could potentially compromise participant protection, especially among marginalized groups. Key areas of concern include the need for more robust community engagement practices, clearer protections for vulnerable populations, and more explicit guidelines around post-trial access to investigational treatments. These challenges highlight the potential risks of exploitation and raise ethical dilemmas within clinical research.

Addressing these challenges necessitates comprehensive reforms. Recommendations include the supervised consent process with oversight from regulatory bodies to ensure ethical compliance, the introduction of objective tests to verify participants' understanding, and mandating audio-visual documentation of the consent process to enhance transparency and accountability. Furthermore, advocating for stronger protections for vulnerable

participants, establishing independent monitoring bodies, and encouraging greater community engagement are pivotal steps toward fostering an ethical research environment.

India stands on the precipice of becoming a global leader in ethical clinical research, striving for a future where clinical trials are synonymous with the highest ethical standards. This vision champions inclusivity, transparency, and respect for participant rights, aiming for a research ecosystem where the pursuit of scientific knowledge harmoniously aligns with unwavering ethical integrity. The collective commitment to these reforms will not only safeguard participants' rights and well-being but also bolster India's credibility and leadership in the global arena of clinical research. Upholding the dignity and rights of every participant, the ethical imperatives guiding clinical trials underscore the profound responsibility to conduct research that is both scientifically rigorous and ethically sound, ensuring that the quest for knowledge never compromises human dignity.

Keywords: Clinical Trials, Informed Consent, Ethical Considerations, Regulatory Framework, Issues and Challenges.

I. INTRODUCTION

Clinical trials are pivotal in the landscape of medical research, serving as the primary pathway for advancing patient care through the development of new medications, treatments, and medical devices. Fundamentally, a clinical trial is a research study performed on human volunteers designed to answer specific health questions. These studies are the final step in a long process that begins with research in a lab. Before any new treatment is made available to the public, it must undergo rigorous testing in clinical trials to ensure its safety and efficacy.

The significance of clinical trials in medical research cannot be overstated. They allow researchers to determine the therapeutic benefits of new treatments, understand their side effects, and establish the correct dosage by using methodologies that minimize bias, thus ensuring the reliability of the findings. Clinical trials are structured into phases - from Phase I, which assesses safety and dosage, to Phase IV, which monitors long-term effects and effectiveness in the population.¹ This phased approach helps to gradually build knowledge about a new treatment's safety and efficacy.

II. HISTORIC EVOLUTION

The concept of conducting experiments to test the efficacy of treatments dates back to antiquity, with one of the earliest documented trials being the biblical account of Daniel refusing the king's diet to demonstrate the health benefits of vegetables and water.² However, the modern clinical trial's foundation is often attributed to James Lind's scurvy trial in 1747 aboard the

¹ *Clinical Trials in India: Document Requirements*, Morulaa HealthTech, available at <https://morulaa.com/indian-medical-device-market/clinical-trials-in-india-document-requirements/>, (last visited Apr. 1, 2024).

² Daniel 1:8-16, Book of Daniel, Old Testament, Hebrew Bible and Christian Biblical Canons, available at <https://www.biblegateway.com/passage/?search=Daniel%201:8-10&version=ERV>, (last visited Apr. 1, 2024).

HMS Salisbury.³ Lind systematically compared treatments for scurvy, providing one of the first instances of controlled clinical experimentation. Despite this early innovation, the development of clinical trials remained slow until the 20th century.

The 20th century marked significant advancements in clinical research, influenced heavily by the ethical violations observed in studies such as the Tuskegee Syphilis Study⁴ and the Nazi experiments during World War II. These events underscored the critical need for ethical oversight in research involving human subjects. In response, the Nuremberg Code⁵ was established in 1947, laying down tenets for the ethical conduct of research, including the necessity of voluntary consent.

The Declaration of Helsinki, first adopted in 1964 by the World Medical Association,⁶ further refined ethical guidelines for medical research involving human subjects, emphasizing informed consent, the importance of research protocols, and the need for review by an independent committee. Subsequent revisions have updated these guidelines to address emerging ethical considerations and challenges.

The evolution of legal frameworks governing clinical trials has been similarly dynamic, aimed at protecting participants and ensuring research integrity. In the United States, the establishment of the Food and Drug Administration (FDA)⁷ and the enactment of the Federal Food, Drug, and Cosmetic Act provided regulatory oversight. In India, the Central Drugs Standard Control Organization (CDSCO)⁸ oversees clinical trials, guided by regulations such as the New Drugs and Clinical Trials Rules, 2019,⁹ which align with international standards and aim to ensure the safety, rights, and well-being of trial participants.

III. REGULATORY LANDSCAPE

The regulatory framework governing clinical trials in India is comprehensive, involving various acts, guidelines, and rules that ensure participants' safety, rights, and well-being while facilitating the advancement of medical science. This section delves into the pivotal legislations and guidelines that shape the conduct of clinical trials in the country.

³ James Lind's scurvy trial, Open Mind BBVA, July 12, 2016, available at <https://www.bbvaopenmind.com/en/science/leading-figures/james-lind-and-scurvy-the-first-clinical-trial-in-history/>, (last visited Apr. 1, 2024).

⁴ Elizabeth Nix, *Tuskegee Experiment: The Infamous Syphilis Study*, History, June 13, 2023, available at <https://www.history.com/news/the-infamous-40-year-tuskegee-study>, (last visited Apr. 2, 2024).

⁵ The Nuremberg Code (1947), available at <https://www.cirp.org/library/ethics/nuremberg/>

⁶ *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, World Medical Association, 18th WMA General Assembly, Helsinki, Finland, June 1964, available at <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>, (last visited Apr. 2, 2024).

⁷ U.S. Food and Drug Administration, available at <https://www.fda.gov/>

⁸ Central Drugs Standard Control Organization, available at <https://cdsco.gov.in/opencms/opencms/en/Home>

⁹ New Drugs and Clinical Trials Rules, 2019, available at <https://www.cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/>

3.1) Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940, serves as one of the earliest statutory frameworks governing the safety, efficacy, and quality of drugs and cosmetics in India. This act outlines the standards for drugs and cosmetics manufactured and sold within the country, as well as the regulatory mechanisms for approval, manufacture, and distribution.¹⁰

3.1.a) Schedule Y:

Before introducing the New Drugs and Clinical Trials (NDCT) Rules, 2019, Schedule Y of the Drugs and Cosmetics Act played a crucial role in regulating clinical trials. It specified guidelines for conducting clinical trials, including the requirements for permission, ethical considerations, the process of obtaining informed consent, monitoring of trials, and reporting of adverse drug reactions.¹¹

3.1.b) Approval Process for New Drugs:

The act establishes an approval process for new drugs, which inherently includes clinical trials to assess their safety and efficacy. This process is overseen by the Central Drugs Standard Control Organization (CDSCO), ensuring that any new drug introduced to the Indian market meets specified safety and efficacy standards.¹²

3.1.c) Ethical Manufacturing Practices:

The act mandates adherence to Good Manufacturing Practices (GMP) laid down in Schedule M, which are critical for ensuring the quality and safety of drugs used in clinical trials. This adherence minimizes the risk of contamination or quality compromise that could affect trial outcomes and participant safety.¹³

3.1.d) Regulation of Import:

Under the third chapter, the Drugs and Cosmetics Act also regulates the import of drugs and cosmetics, including those for clinical trial purposes. Imported drugs for clinical trials must comply with the same quality, safety, and efficacy standards as domestically produced drugs, ensuring consistency in trial materials.¹⁴

3.2) Medical Council of India Act, 1956

The Medical Council of India Act, 1956, was a pivotal statute aimed at consolidating and amending the laws relating to the medical profession in India. While the act itself focuses on the standards of medical education, the registration of doctors, and the oversight of medical practice in India, its implications for clinical trials are significant, particularly through the ethical guidelines it fosters for medical practitioners.¹⁵

¹⁰ The Drugs and Cosmetics Act, 1940, No. 23 Acts of Parliament, 1940, (India)

¹¹ The Drugs and Cosmetics Act, 1940, No. 23 Acts of Parliament, 1940, (India), Schedule Y

¹² *Supra* note 10.

¹³ The Drugs and Cosmetics Act, 1940, No. 23 Acts of Parliament, 1940, (India), Schedule M

¹⁴ The Drugs and Cosmetics Act, 1940, No. 23 Acts of Parliament, 1940, (India), Chapter III - Import of Drugs and Cosmetics

¹⁵ Medical Council of India Act, 1956, No. 102 Acts of Parliament, 1956 (India).

3.2.a) Professional Conduct:

Section 20A empowers the Medical Council of India to prescribe standards of professional conduct, etiquette, and a code of ethics for medical practitioners. While not explicitly mentioned, these standards of conduct could encompass ethical obligations for physicians involved in clinical trials as investigators or researchers. For example, maintaining professional integrity, ensuring informed consent, protecting patient privacy/confidentiality, avoiding exploitation, and transparently reporting trial data. The MCI's ethical guidelines, although general, lay the foundation for ethical practices that are crucial when conducting clinical research involving human participants.¹⁶

3.2.b) Maintenance of Medical Registers:

The Act mandates the maintenance of State Medical Registers (Section 22)¹⁷ and the Indian Medical Register (Section 23)¹⁸ by MCI. Only medical practitioners registered under these provisions are legally allowed to practice medicine in India. This registration requirement indirectly extends to physicians serving as investigators or researchers in clinical trials on drugs or medical devices. Unregistered or deregistered medical practitioners would be barred from participating in or conducting clinical trials as per the Act's regulations. This ensures a basic level of oversight and qualification for those interacting with clinical trial participants.

3.2.c) Standards of Medical Education:

Section 19A empowers the Medical Council of India to prescribe standards of medical education, including the curriculum, staff, equipment, and standards for granting recognized medical qualifications. While focused on education, this could indirectly impact clinical trials by ensuring medical students and prospective physicians receive adequate training in research ethics, guidelines for clinical studies, and principles like informed consent. Robust training on these aspects helps build an ethical foundation for future medical practitioners who may go on to conduct or participate in clinical trials.¹⁹

3.3) Central Council for Indian Medicine Act, 1970

The Central Council for Indian Medicine Act, 1970, is a legislative framework established to regulate the education and practice of the Indian Systems of Medicine, including Ayurveda, Siddha, Unani, and Sowa-Rigpa. This act led to the formation of the Central Council for Indian Medicine (CCIM), which is pivotal in standardizing and promoting traditional medical practices in India. While its primary focus is not directly on clinical trials, the act, and the council's regulations have significant implications for the research and development of traditional medicines, aligning them with contemporary standards of efficacy and safety.²⁰

¹⁶ Medical Council of India Act, 1956, No. 102 Acts of Parliament, 1956 (India), s. 20A

¹⁷ Medical Council of India Act, 1956, No. 102 Acts of Parliament, 1956 (India), s. 22

¹⁸ Medical Council of India Act, 1956, No. 102 Acts of Parliament, 1956 (India), s. 23

¹⁹ Medical Council of India Act, 1956, No. 102 Acts of Parliament, 1956 (India), s. 19A

²⁰ The Indian Medicine Central Council Act, 1970, No. 48 Acts of Parliament, 1970 (India).

3.3.a) Standardization of Education and Practice:

The act mandates the standardization of educational qualifications and practice in Indian Systems of Medicine. By ensuring that practitioners and educators adhere to defined standards, the act indirectly supports the foundation for high-quality clinical research in these traditional medicine systems. Standardized practices enable more reliable and scientifically valid clinical trials, which is essential for integrating traditional medicines into mainstream healthcare.²¹

3.3.b) Regulation of Indian Medicine Pharmaceuticals:

Through its regulatory powers, the CCIM contributes to the framework that oversees the production and use of pharmaceuticals derived from the Indian Systems of Medicine. This regulation is crucial for ensuring that any herbal or traditional formulations used in clinical trials meet safety and quality standards similar to those expected of conventional medicines.²²

3.3.c) Professional Conduct and Ethical Guidelines:

Although the CCIM primarily focuses on educational and practice standards, the ethical principles it upholds for practitioners also extend to research within the Indian Systems of Medicine. Practitioners engaged in clinical trials of traditional medicines are expected to adhere to ethical standards that ensure participant safety, informed consent, and scientific integrity. These principles are aligned with broader ethical guidelines governing clinical research in India.²³

3.4) Good Clinical Practices Guidelines, 2001

The Good Clinical Practice (GCP) Guidelines, issued by the Central Drugs Standard Control Organization (CDSCO) in 2001, represent a significant milestone in the evolution of clinical research in India. These guidelines are harmonized with international standards, specifically, the International Council for Harmonisation's Good Clinical Practice (ICH GCP), ensuring that clinical trials conducted in India adhere to global ethical and scientific quality standards. The GCP Guidelines are crucial for protecting the rights, safety, and well-being of trial participants and ensuring the integrity of clinical trial data.²⁴

3.5) Right to Information Act, 2005

The Right to Information Act (RTI), 2005, is a landmark legislation in India that promotes transparency and accountability in the workings of the government and public authorities by empowering citizens to request information. While not directly related to clinical trials, the provisions of the RTI Act hold significant implications for the conduct and oversight of clinical research in India, particularly in fostering transparency and public trust.²⁵

²¹ The Indian Medicine Central Council Act, 1970, No. 48 Acts of Parliament, 1970 (India), s. 22

²² The Indian Medicine Central Council Act, 1970, No. 48 Acts of Parliament, 1970 (India), s. 36

²³ The Indian Medicine Central Council Act, 1970, No. 48 Acts of Parliament, 1970 (India), s. 26

²⁴ ICH-E6 Good Clinical Practice (GCP), available at https://database.ich.org/sites/default/files/ICH_E6-R3_GCP-Principles_Draft_2021_0419.pdf

²⁵ The Right to Information Act, 2005, No. 22 Acts of Parliament, 2005 (India).

3.6) New Drugs and Clinical Trials Rules, 2019

The New Drugs and Clinical Trials Rules, 2019, introduced by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare, Government of India, marks a significant overhaul of the regulatory framework governing clinical trials in India. Aimed at ensuring patient safety while promoting ethical and scientific standards, these rules streamline the approval process for new drugs and clinical trials, fostering innovation and making India a favorable destination for clinical research.²⁶

IV. THE THIRD SCHEDULE OF NDCT RULES, 2019

The landscape of clinical trials in India has been significantly shaped and standardized by the New Drugs and Clinical Trials (NDCT) Rules, 2019, especially with the introduction of the Third Schedule. This comprehensive framework not only delineates the ethical and procedural mandates essential for conducting clinical trials but also emphasizes protecting participants' rights and safety. The Third Schedule is pivotal, outlining the principles of informed consent and encompassing additional critical aspects such as the responsibilities of investigators, the intricacies of the Investigator's Brochure, ethical oversight, and the detailed protocols that guide the conduct of clinical trials.

The core components that define the integrity and ethical underpinning of clinical trials, the focus shifts to critical elements crucial for conducting research that respects and protects participants. Informed consent emerges as a fundamental aspect, highlighting the importance of participant autonomy and informed decision-making. Beyond informed consent, comprehensive health assessments, ongoing monitoring, access to free medical assistance, and equitable compensation mechanisms are vital for safeguarding participants' rights and well-being. Exploring these elements thoroughly unveils best practices and pinpoints where current procedures might need enhancement. This scrutiny goes beyond reinforcing ethical standards in clinical trials; it aims to improve their efficacy and build public and participant trust in medical research.²⁷

4.1) Informed Consent

Informed consent is a cornerstone of ethical clinical research, embodying the principle that participants should enter into research voluntarily and with a full understanding of what it entails. Under the Third Schedule of the New Drugs and Clinical Trials (NDCT) Rules, 2019, India has laid down comprehensive guidelines to ensure that informed consent in clinical trials is obtained and documented in a manner that upholds the highest ethical standards.

4.1.a) Comprehensiveness:

The consent process must cover all aspects of the trial, including its purpose, duration, required procedures, key contacts, and the risks and potential benefits. It should also explain the right of the participant to refuse to participate or withdraw from the trial at any time.

²⁶ *Supra* note 9, at 5.

²⁷ New Drugs and Clinical Trials Rules, 2019, Third Schedule

4.1.b) Language and Understanding:

The consent form and any other informational materials provided to the participants must be in a language that is understandable to them. Complex medical and legal jargon should be avoided to ensure that the participant can make an informed decision.

4.1.c) Documentation:

Written informed consent must be obtained from each participant before they are enrolled in the trial. The NDCT Rules specify that the consent form must be signed and dated by the participant or their legally acceptable representative in the presence of an impartial witness.

4.1.d) Special Populations:

Additional considerations are required for vulnerable populations, including minors, individuals with cognitive impairments, and economically or educationally disadvantaged persons. In such cases, the NDCT Rules require that consent is obtained in a manner that reflects the participant's best interests and affords additional protections to ensure their rights are safeguarded.

4.1.e) Audio-Visual Recording:

For certain types of clinical trials, such as those involving new chemical entities or new molecular entities, the process of obtaining informed consent must also be audio-visually recorded. This requirement adds an additional layer of transparency and accountability to the consent process.

4.1.f) Voluntariness:

Ensuring the voluntary nature of participation is paramount. Participants should not feel coerced or unduly influenced to participate, and they should be made aware that their care will not be compromised should they decide not to participate or withdraw from the trial at any stage.

4.1.g) Privacy and Confidentiality:

The confidentiality of information provided by participants during the consent process and their privacy must be maintained in accordance with applicable laws and regulations.

4.1.h) Participant Rights:

The informed consent process must emphasize the participant's rights, including the right to receive prompt medical care in the event of any trial-related injury, the right to ask questions and receive clear answers, and the right to be informed of the trial results upon completion.

V. LEGAL AND ETHICAL FRAMEWORK

The governance of CT in India is fundamentally anchored in the nation's Constitution, with Article 21 playing a pivotal role in establishing the legal basis for bodily autonomy and the right to life. This constitutional provision is crucial in the context of clinical trials, providing a robust foundation for ethical and legal norms that protect participants' rights and dignity.

5.1) Article 21 of the Indian Constitution: A Pillar of Protection

Article 21 states, "No person shall be deprived of his life or personal liberty except according to the procedure established by law."²⁸ Over the years, the Supreme Court of India has expansively interpreted this article, extending its protection to encompass the right to health, privacy, and dignified treatment, thereby embedding the principles of bodily autonomy and informed consent within the legal fabric of the country.

5.2) Bodily Autonomy and Informed Consent

Bodily autonomy, as protected under Article 21, asserts an individual's right to self-governance over their own body without coercion or undue influence.²⁹ In clinical trials, this right is actualized through the process of informed consent, where participants are provided with all necessary information about the trial in a manner that is understandable and respectful of their capacity to make decisions. This process is not a mere formality but a fundamental expression of respect for participants' autonomy, dignity, and rights.

The legal framework, enriched by Article 21, ensures that clinical trials are conducted in a manner that respects the individual's autonomy while striving for the larger goal of medical advancement. It places a legal obligation on researchers, sponsors, and ethics committees to prioritize participants' rights and well-being, aligning clinical research with constitutional values.³⁰

5.3) The Contractual Dimension

Moving from the constitutional to the contractual dimension brings into focus the Indian Contract Act, which governs agreements between parties, including those relating to clinical trial participation.³¹ The act stipulates that for a contract to be valid, consent must be free of coercion, fraud, undue influence, mistake, and misrepresentation. This legal requirement reinforces the ethical imperative of informed consent in clinical trials, ensuring that participants' agreement to partake in research is an expression of their free will, aligned with the constitutional protections afforded by Article 21.

5.3.a) Section 10 (Essentials of a Valid Contract):

This section stipulates that for any agreement to be considered a valid contract, it must be made with the free consent of the parties. In the context of clinical trials, this underscores the necessity for participants' consent to be obtained freely, without any form of coercion, undue influence, fraud, misrepresentation, or mistake. This aligns with the ethical requirement of informed consent, ensuring that participants fully understand and agree to the trial terms of their own volition.³²

²⁸ INDIA CONST. art.21

²⁹ *Id* at 28

³⁰ *Id*

³¹ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India).

³² The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 10

5.3.b) Sections 14, 15, and 16 (Free Consent and Its Impediments):

Elaborating on what constitutes free consent,³³ Section 14 emphasizes that consent is considered free when it is not caused by coercion (as defined in Section 15)³⁴, undue influence (as per Section 16),³⁵ fraud (Section 17),³⁶ misrepresentation (Section 18),³⁷ or mistake (Sections 20 to 22).³⁸ This legal provision is crucial in clinical trials, demanding transparency and honesty from researchers in conveying trial information, thereby protecting participants from manipulative practices.

5.3.c) Section 23 (Lawful Consideration and Object):

This section asserts that for any contract to be enforceable, its consideration and object must be lawful. This is relevant in ensuring that clinical trials are designed with lawful objectives, including the advancement of medical knowledge or the development of new treatments, and do not involve any activities that would be considered illegal, immoral, or opposed to public policy.³⁹

5.4) Adaptation to Digital Consent:

The digital era has seen a shift towards e-contracts, which are electronic versions of traditional contracts, including those used for obtaining consent in clinical trials. E-contracts offer a platform for participants to review, understand, and agree to the trial terms electronically, potentially increasing accessibility and understanding through interactive and tailored consent processes.

5.4.a) Legal Recognition and Enforcement:

Section 10A of the Information Technology Act, 2000, provides the legal basis for the validity and enforceability of electronic contracts in India, acknowledging that agreements formed electronically hold the same legal stature as paper-based contracts. This recognition is crucial for ensuring that e-contracts used in clinical trials meet the legal requirements of informed consent.⁴⁰

5.4.b) Challenges and Opportunities:

While e-contracts can enhance the consent process through personalized information delivery and ease of access, they also raise challenges regarding ensuring comprehension and voluntary agreement, particularly among populations with limited digital literacy. The legal framework requires that these digital consent processes are designed to be inclusive, comprehensible, and capable of capturing the free and informed consent of all participants, regardless of their familiarity with digital technologies.

³³ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 14

³⁴ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 15

³⁵ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 16

³⁶ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 17

³⁷ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 18

³⁸ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 20, 21, 22

³⁹ The Indian Contract Act, 1872, No. 9 Acts of Parliament, 1872 (India), s. 23

⁴⁰ The Information Technology Act, 2000, No. 21 Acts of Parliament, 2000 (India), s. 10A

VI. CASE STUDIES AND LEGAL PRECEDENTS

The landscape of clinical trials and informed consent in India has been significantly shaped by landmark judgments. These cases have not only clarified the legal principles surrounding medical ethics and patient rights but have also highlighted the evolving nature of informed consent. Below, we analyze key judgments and draw parallels with international practices.

6.1) Maneka Gandhi v. UOI

This landmark judgment expanded the interpretation of the right to life under Article 21 of the Indian Constitution, including the right to live with dignity. It underscores the necessity of ensuring that clinical trial protocols respect participants' rights and dignity, reinforcing the ethical and legal obligations to secure informed consent.⁴¹

6.2) Ram Bihari Lal v Dr. J. N. Srivastava

This case dealt with medical negligence, emphasizing the doctor's duty to inform the patient about the risks of a medical procedure. It highlights the importance of disclosing all potential risks to trial participants, aligning with informed consent principles.⁴²

6.3) C A Muthu Krishnan v M. Rajyalakshmi

Focused on the accountability of medical professionals, this case further emphasized the need for informed consent and ethical medical practices. It reinforces the legal requirement for clear communication and consent in clinical research.⁴³

6.4) Chandra Shukla v UOI

This case is pivotal for understanding the government's responsibility in protecting citizens' health rights. It suggests that regulatory bodies must ensure clinical trials are conducted ethically, prioritizing participant safety.⁴⁴

6.5) Samaira Kohli v Dr. Prabha Manchanda and Another

This Supreme Court case redefined consent in medical procedures, asserting that consent must be informed and specific to the procedure being performed. It mandates that participants must be fully informed about the specific interventions and potential risks in a trial.⁴⁵

⁴¹ Maneka Gandhi v. UOI, 1978 AIR 597, 1978 SCR (2) 621

⁴² Ram Bihari Lal v Dr. J. N. Srivastava, AIR 1985 Madhya Pradesh 150, (1985) MPLJ 288, (1985) ACJ 424, (1985) 1 CURCC 987, (1985) JAB LJ 259

⁴³ C A Muthu Krishnan v M. Rajyalakshmi, AIR 1999 AP311, 1998(4)ALT283, AIR 1999 Andhra Pradesh 311, (1998) 4 ANDH LT 283 (2000) 1 MARRILJ 380, (2000) 1 MARRILJ 380

⁴⁴ Chandra Shukla v Union of India, 1985 AIR 1351, 1985 SCR SUPPL. (2) 367, AIR 1985 Suprem Court 1351, 1985 LAB. I. C. 1625, (1986) 29 DLT 6, 1985 SCC (L&S) 919, 1985 (3) SCC 721

⁴⁵ Samaira Kohli v Dr. Prabha Manchanda and Another, AIR 2008 Supreme Court 1385, 2008 AIR SCW 855

6.6) Paschim Banga Khet Mazdoor Samity and Ors v State of West Bengal and Another
The Supreme Court emphasized the state's obligation to provide medical services to preserve life. This underscores trial sponsors' and researchers' ethical and legal responsibilities to ensure participant well-being.⁴⁶

6.7) Pt. Parmanand Katara v Union of India. AIR 1989 SC 2039

This judgment reinforced the importance of providing immediate medical care to save lives, regardless of circumstances. It highlights the necessity for an immediate medical response during a trial in the event of adverse effects.⁴⁷

6.8) TT Thomas (Dr.) vs Elisa

The case focused on the consent process in medical treatment, emphasizing that patients should know and comprehend the treatment offered. It underlines the importance of ensuring that trial participants fully understand the nature and purpose of the trial, reinforcing the concept of informed consent.⁴⁸

VII. ISSUES AND CHALLENGES

The implementation of the New Drugs and Clinical Trials (NDCT) Rules, 2019, marked a significant advancement in India's regulatory framework for clinical trials. However, several challenges persist that require attention to ensure the safety, rights, and well-being of participants, especially those from marginalized groups. Addressing these challenges is crucial for building a more ethical and equitable landscape for clinical research in India.

7.1) Inadequate Community Engagement:

The rules may not sufficiently emphasize the need for community engagement and consultation, particularly in trials involving indigenous or rural populations. This gap can lead to a lack of understanding and mistrust among these communities.

7.2) Vulnerable Populations:

There is a need for clearer guidelines that specifically protect vulnerable populations, including children, the elderly, and those with cognitive impairments, ensuring that their participation is truly informed and voluntary.

7.3) Post-Trial Access:

The provisions for post-trial access to investigational drugs for participants are not robustly defined, potentially leaving participants without access to successful treatments once a trial concludes.

⁴⁶ Paschim Banga Khet Mazdoor Samity and Ors v State of West Bengal and Another, 1996 SCC (4) 37, JT 1996 (6) 43, AIR 1996 Supreme Court 2426

⁴⁷ Pt. Parmanand Katara v Union of India, 1989 AIR 2039, 1989 SCR (3) 997, AIR 1989 Supreme Court 2039

⁴⁸ Dr. T.T. Thomas vs Smt. Elisa And Ors, I(1987)ACC445, AIR1987KER52, AIR 1987 Kerala 52, (1987) 2 TAC 50, (1987) 1 ACC 445

7.4) Socio-Economic Disparities

Economic and social disparities in India can lead to unequal outcomes in clinical trial participation. Marginalized communities might not have the same access to information about trials, might not fully understand the consent process due to language and literacy barriers, or might participate in trials primarily due to financial incentives without fully considering the risks involved. This scenario can skew trial demographics and potentially exploit the most vulnerable populations.

VIII. RECOMMENDATIONS FOR REFORM

8.1) Enhanced Protection for Vulnerable Groups:

Develop and implement enhanced guidelines that provide clear protections for vulnerable populations participating in clinical trials, such as women, children, and persons with special needs. These guidelines should outline specific consent processes, including the use of lay language and visual aids to ensure understanding and mandate the presence of an advocate during the consent process for participants from vulnerable groups.

8.2) Strengthen Community Engagement:

Encourage the establishment of Community Advisory Boards for trials that significantly impact certain populations or communities. These boards can provide valuable insights into community concerns and expectations, facilitating ethical community engagement.

8.3) Improve Transparency and Public Reporting:

Mandate the registration of all clinical trials in a publicly accessible national registry before their initiation. This registry should include comprehensive details about the trial's purpose, methodology, funding sources, and ethical approvals, enhancing transparency and public trust.

8.4) Enhancing Informed Consent Processes:

Standardized Templates: Introduce standardized informed consent templates that are culturally sensitive and available in multiple regional languages, ensuring clarity and comprehension for participants from diverse backgrounds.

8.5) Supervised Consent Process

To elevate the standard of the informed consent process, it is proposed that consent sessions be conducted in the presence of an authorized representative from the Drugs Controller General of India (DCGI) and the Central Drugs Standard Control Organization (CDSCO). This measure aims to ensure that the process adheres strictly to the prescribed ethical and procedural guidelines, eliminating potential negligence.

The involvement of DCGI and CDSCO representatives serves to ensure that all necessary information is accurately communicated to the participant and that the process is free from undue influence or misinformation. This could involve a random selection of clinical trials for supervised consent processes or focus on trials that involve vulnerable populations, novel interventions, or have higher risk profiles. Such oversight would safeguard participant rights

and enhance trust in the clinical trial process, ensuring transparency and accountability from the outset.

8.6) Comprehension Verification

Recognizing the necessity of participant comprehension in the informed consent process leads to the recommendation of implementing an objective test round. This test would assess whether participants have truly understood the information provided to them.

For literate participants, a brief written test comprising straightforward questions related to the trial information could be administered. For participants who are illiterate, an oral version of the test, possibly in the form of a discussion or interview, would ensure their understanding is adequately assessed.

8.7) Audio-Visual Documentation of Consent

The proposal for mandatory audio-visual recording of the informed consent process, including the comprehension test, introduces an additional layer of transparency and accountability.

The recording should capture the entire consent process, clearly documenting the information provided to the participant and their engagement during the process. Importantly, the objective test verifying participant understanding should also be recorded, providing visual evidence of their comprehension. Care must be taken to ensure that these recordings are handled with the utmost respect for participant privacy, securely stored, and used solely for the purposes of verifying the consent process.

IX. CONCLUSION

The heart of clinical research beats with the principles of informed consent and ethical conduct. The critical role of informed consent cannot be overstated. It is the keystone that ensures participant autonomy, safeguarding individuals' rights to make educated decisions about their participation in research.

Alongside this, the ethical conduct within clinical trials serves as the guardian of dignity and safety, ensuring that every trial is not just a pursuit of scientific knowledge but a testament to our collective ethical commitment. Landmark judgments and evolving legal provisions have further fortified this ethical bastion, continually shaping a more accountable and participant-centric research environment.

*"Human rights are not only violated by terrorism, repression, or assassination but also by unfair economic structures that create huge inequalities."*⁴⁹ This poignant statement by Pope Francis encapsulates the essence of ethical considerations in clinical trials, highlighting the imperative to address and rectify inequalities, including those in healthcare research. It underscores the need for a fair and just approach that respects and protects all participants' inherent dignity and rights.

⁴⁹ José Santiago, *20 memorable quotes from Pope Francis*, World Economic Forum, Sept 22, 2015, available at <https://www.weforum.org/agenda/2015/09/19-memorable-quotes-from-pope-francis/>, (last visited Apr. 4, 2024).