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DIGITAL CONSENT AND AI-DRIVEN DRUG TRIALS: REVISITING PATIENT RIGHTS UNDER THE NDCT RULES 2019 IN THE AGE OF ARTIFICIAL INTELLIGENCE

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ABSTRACT:
Pharmaceutical research in India is changing as a result of the incorporation of artificial intelligence into clinical trial procedures, such as patient recruiting, risk stratification, adverse-event monitoring, and remote or e-consent platforms. However, the regulatory framework controlling patient rights has not kept up. Through ethical committee registration and standardized consent procedures, the New Drugs and Clinical Trials (NDCT) Rules, 2019 improved participant safeguards. However, these measures were designed for human-mediated disclosure, not AI-mediated decision-making. Consent validity, data privacy, and accountability are three interconnected aspects of this regulatory gap that are examined in this paper's doctrinal, gap-analysis study.
First, it argues that India's underdeveloped common-law doctrine of informed consent, compounded by the absence of AI-specific disclosure norms, leaves participants without meaningful notice of algorithmic involvement in their care. Second, it interrogates whether the Digital Personal Data Protection Act, 2023, read with the NDCT Rules, offers a proportionate legal basis for the large-scale linkage of health records, genetic data, and monitoring systems that AI-driven trials require. Third, it examines the accountability vacuum created by opaque, “black-box” AI systems influencing eligibility and risk decisions, where liability among sponsors, investigators, and technology developers remains unassigned. Drawing comparative insight from the EU AI Act, the GDPR, and evolving United States FDA guidance, the paper proposes a reform framework to recalibrate India's consent, privacy, and liability standards for an AI-enabled clinical trial ecosystem, ensuring patient autonomy and protection keep pace with technological transformation in drug development.

KEYWORDS: digital consent, artificial intelligence in clinical trials, NDCT Rules 2019, data privacy, algorithmic accountability

INTRODUCTION

Clinical trials are situated at the nexus between personal vulnerability and scientific advancement. When someone volunteers to participate, they entrust their body, their data, and frequently their hope for treatment to a research organization that must adhere to safety and disclosure regulations. The New Drugs and Clinical Trials (NDCT) Rules, 2019, which were developed in the wake of ten years of litigation over unethical and inadequately supervised trials—most notably the Supreme Court's proceedings in Swasthya Adhikar Manch v. Union of India—are primarily responsible for embodying this promise in India. The 2019 Rules defined compensation duties for trial-related damage or death, strengthened registration requirements for ethics committees, and required audio-visual recording of consent in certain trial categories.
The degree to which artificial intelligence would be incorporated into clinical trials within a few years of the Rules' announcement is something they could not have predicted. These days, machine-learning techniques help identify eligible participants from electronic health records, forecast which people are at risk of adverse outcomes, and create or simplify the consent paperwork that participants must sign. Evidence from throughout the world indicates that these tools are already having quantifiable effects on participant communication and trial design (Olawade et al., 2026).
However, an analysis of information-consent forms from a large international trial registry revealed that about a fifth did not indicate any AI-related risk at all, and over half did not reveal the kind or intended usage of the AI system involved (Su et al., 2026). India, where the regulatory discussion on AI in clinical research has just started, is unlikely to do better if this is the status of disclosure globally. This paper poses a specific but important question: is a trial participant whose recruitment, monitoring, or risk assessment is influenced by an AI system sufficiently protected by the consent, privacy, and accountability architecture established by the NDCT Rules, 2019 and strengthened by the Digital Personal Data Protection Act, 2023 ("DPDP Act")? Before putting up a reform approach based on comparable practice, the article makes the case that it doesn't and highlights three distinct aspects of the gap: consent validity, data privacy, and accountability.

1.2 Research Objectives

- To examine whether the consent mechanism under Schedule V of the NDCT Rules, 2019, adequately captures AI-mediated recruitments and risk stratification in Clinical Trials.

- To evaluate whether the DPDP Act 2023 provides adequate safeguards for large-scale data linkage that an AI-driven clinical trial requires.
- To draw comparative insights from the EU AI Act and GDPR to identify structural reforming elements.
- To analyse the accountability vacuum created by opaque black-box AI systems and to identify liability of sponsors, investigators, etc.
- To propose a targeted reform framework recalibrating India's consent, privacy and liability standard for AI-enabled Clinical Trials.

1.3 Research Questions

- Is a trial participant whose recruitment, monitoring, or risk assessment is influenced by an AI system sufficiently protected by the consent, privacy, and accountability architecture of the NDCT Rules, 2019, as supplemented by the DPDP Act, 2023?
- Does the "silent algorithm problem" (non-disclosure of AI involvement in recruitment/classification) constitute a disclosure failure under Schedule V?
- Is the current framework capable of verifying identity, capacity, and voluntariness in purely digital/remote e-consent transactions
- Do India's ethics committees possess the institutional and technical capacity to review AI-enabled protocols for privacy and bias risk?

1.4 Research Gaps

Schedule V has no requirement to disclose AI involvement in recruitment, risk classification, or monitoring.
Ethics committees have no mandated technical/data-science expertise to assess AI-specific privacy or bias risk.
No bridging protocol exists between the DPDP Act and NDCT Rules addressing proportionality of data linkage for AI model training/validation.

1.5 RESEARCH METHODOLOGY

Doctrinal legal research, using a normative gap-analysis method rather than empirical fieldwork.

2. The Consent Architecture under the NDCT Rules, 2019

The Drugs and Cosmetics Rules, 1945's older, more disjointed consent rules were replaced by the NDCT Rules, 2019, which combined the criteria for informed consent, ethics committee supervision, and compensation into a single framework. The structure and substance of the informed consent statement are outlined in Schedule V of the Rules, which mandates that the trial's goal, the procedures involved, any known hazards, and the participant's right to withdraw without affecting continued care be disclosed. As a direct response to previous discoveries of forceful or ignorant enrollment, audio-visual recording of the consent procedure is required for trials of new chemical entities and for vulnerable participant groups.

Despite these advancements, Indian scholarship has long noted that the nation lacks a well-developed common-law doctrine of informed consent specific to clinical research. As a result, the legal remedies available to an injured or deceived participant are underdeveloped and primarily rely on the general law of torts and the constitutional right to health (Bhakuni, 2020). According to an empirical review of clinical research ethics in India, gaps in ethics committee capacity continue even under the stricter 2019 framework, and supervisory practice—rather than statutory text alone—determines whether consent is truly informed (Paramasivan et al., 2021).

In other words, while the Rules outline what must be disclosed, they do not address the more fundamental question of what a participant must truly comprehend for consent to be deemed valid, nor do they take into account a situation where a portion of the disclosed information comes from or is mediated by an automated system instead of a treating investigator.

3. The Expanding Role of Artificial Intelligence in Clinical Trials

Artificial intelligence is becoming more and more integrated throughout the trial lifecycle; it is no more a stand-alone instrument in drug development. Recruitment algorithms significantly cut down on the time and expense of enrollment by mining administrative claims data and electronic health records to find people who fit a trial's eligibility requirements (Olawade et al., 2026). Predictive methods identify trial participants who are more likely to experience an adverse event, and natural-language systems are being tested to convert complex consent paperwork into summaries that are easier for participants to grasp (Waters, 2025). Before a single human participant is enrolled, AI helps sponsors optimize dose regimens and simulate trial outcomes during the design phase.

These applications are not hypothetical; they are supported by ongoing international studies and are the focus of new international regulatory guidelines, such as suggestions for standardized reporting of AI use in trial protocols similar to the SPIRIT-AI extension. However, there is a dearth of detailed information in the literature regarding the deployment, disclosure, and regulation of these applications within the Indian clinical trial ecosystem. This absence is noteworthy in and of itself because it implies that Indian regulators and ethical committees have not yet addressed the issues that foreign organizations are just starting to address in a systematic manner.

4. Consent Validity in the Age of AI

The first and most immediate legal issue is whether consent obtained under the NDCT Rules' existing format can be considered valid when an AI system has materially influenced the participant's recruitment, risk classification, or ongoing monitoring. Three specific problems arise.

4.1 The Silent Algorithm Problem

The subject is never told that a machine, not a doctor's independent judgment, initially classified them as acceptable when an algorithm finds or filters possible volunteers before a human investigator ever contacts them. This is a disclosure issue that is different from standard risk disclosure, according to commentators on AI ethics in clinical trials: patients have a right to know not just what the study entails but also that an AI system is engaged in making decisions that impact their care (Su et al., 2026). There is no matching requirement under Schedule V of the NDCT Rules.

4.2 Comprehension in a Digital Consent Environment

Even in cases where AI is made public, understanding is still a challenge. AI-generated summaries increase reading scores and participant comprehension, according to studies employing big language models to simplify permission paperwork (Waters, 2025). However, automated summarization carries a risk of omission or inaccuracy, and a participant relying on an AI-simplified summary may consent to a materially different account of risk than the one contained in the underlying legal document. As a result, the same technology that enhances comprehension may also obscure it. The evidential position of an AI-generated consent summary in relation to the formal consent document it summarizes is not addressed by the NDCT Rules, which were drafted prior to the existence of such technologies.

4.3 Remote and E-Consent

In-person consent that was audio-visually recorded at the trial site was the primary emphasis of the 2019 Rules. As decentralized and distant trial models become more common, consent is being obtained through digital platforms without a human witness physically present to confirm identification, capacity, or voluntariness. Since Indian law has not yet set a norm for verifying identity and decision-making ability in a purely digital consent transaction, there is a procedural gap where AI-enabled employment is most likely to occur.

5. Data Privacy and the Reach of AI-Driven Trials

The legal basis for participant data gathering, aggregation, and reuse by AI systems in clinical trials is the subject of the second element. Any clinically useful AI model requires large, linked datasets. Genetic data, electronic health records, trial-specific monitoring data, and, increasingly, wearable device data are all frequently combined in these databases. The sensitivity of the information involved and the repercussions of any breach or misuse are increased by this connection (Olawade et al., 2026).

The NDCT Rules function in tandem with India's Digital Personal Data Protection Act, 2023, which was passed to create a broad framework for the processing of personal data, including the elevated category of health-related information. The two statutes were not drafted simultaneously, and neither specifically addresses the proportionality issue that AI-driven trials bring up: is the amount and duration of data linkage necessary to train or validate a predictive model commensurate with the initial consent obtained for a single, specific trial purpose? The description of data-handling requirements following a participant's withdrawal varied widely, with a significant percentage of consent agreements offering no information at all, according to a cross-sectional assessment of consent documentation from AI-related trials conducted globally(Su et al., 2026). There is no reason to expect Indian practice to be more consistent, given the absence of any sector-specific guidance bridging the DPDP Act and the NDCT Rules on this question.

Institutional capacity is another issue. The primary purpose of ethics committees established under the NDCT Rules is to evaluate clinical and procedural risk; they are typically ill-equipped to assess cybersecurity architecture, model-training pipelines, or re-identification risks related to AI systems processing linked health data. Due to this capacity gap, the committee responsible for approving the trial may not have the technical expertise to confirm that a protocol complies with the DPDP Act's consent and purpose-limitation requirements in practice.

6. Accountability and the Problem of Algorithmic Opacity

Who is accountable when an AI system's output affects a participant's eligibility, monitoring, or clinical trajectory and that output later proves to be inaccurate, biased, or detrimental? The least developed aspect of Indian law is the third facet. The term "black boxes" is frequently used to describe clinical AI systems because even their developers are unable to adequately describe their internal decision logic. Because of this, it is difficult to test for bias, explain a negative result to a participant, or place blame on the sponsor, investigator, ethics committee, and technology developer.

In order to allow regulators and future researchers to audit what the system did and why, international reporting frameworks have started to address this opacity by requiring standardized disclosure of the AI intervention used in a trial, the nature of human-AI interaction, and a structured account of error analysis. The NDCT Rules do not have a comparable reporting requirement, and India's ethics committee system, which is already dealing with well-established capacity and consistency gaps (Paramasivan et al., 2021), lacks a mechanism for requesting or examining such disclosure.In the absence of a reporting requirement, liability questions default to general principles of tort and contract law, which were not designed with an autonomous, self-updating decision system in mind, and which offer an injured participant little practical certainty about whom to sue or on what theory.

7. Comparative Perspectives

Other jurisdictions provide incomplete but partial reform models. The EU's AI Act places additional transparency and risk-management requirements on AI systems categorized as high-risk, which is likely to include many AI applications used in clinical trials. The EU's General Data Protection Regulation imposes a heightened, explicit consent standard for the processing of health data as a special category. The Food and Drug Administration in the US has started releasing guidelines on the application of AI and machine learning in drug development, including expectations regarding model validation and lifecycle monitoring. However, these guidelines are still mostly non-binding and are constantly changing. None of these frameworks was designed with the Indian regulatory landscape in mind, and wholesale transplantation would be neither feasible nor advisable given differences in trial volume, ethics committee capacity, and digital literacy among participant populations. Their value for this paper lies instead in the structural template they offer: an explicit, heightened consent standard for health data; a risk-tiered obligation of transparency for AI systems; and a lifecycle-based expectation of monitoring and validation. India's reform conversation on AI in clinical trials has yet to engage with any of these three structural elements in a sustained way.

8. Toward a Reform Framework

Building on the gaps identified above, this paper proposes four specific reforms to the existing NDCT Rules and DPDP Act framework, rather than a wholesale redrafting of either instrument.

8.1 Mandatory AI-Specific Disclosure in Consent Documents

Anywhere an AI system significantly affects hiring, risk assessment, or monitoring, Schedule V of the NDCT Rules should be modified to include explicit disclosure, along with a clear explanation of the system's function and recognized limits.

8.2 A Bridging Protocol Between the DPDP Act and the NDCT Rules

A joint sectoral guidance note addressing the proportionality of data linkage specifically for AI-driven trials, including retention limits and requirements for secondary use of trial data in model training, should be released by the Central Drugs Standard Control Organization in collaboration with the data protection authority established under the DPDP Act.

8.3 Technical Capacity within Ethics Committees

Similar to the current Rules' need for independent and lay members, ethics committees evaluating AI-enabled trial protocols should be obliged to include or consult a member with proven expertise in data science or health informatics.

8.4 A Standardised AI Reporting Requirement

Alongside the trial protocol, sponsors should be obliged to submit a structured AI-disclosure annexure outlining the function, validation status, and human-AI interaction model of the AI system. This would provide a documentary foundation upon which culpability might later be evaluated in the event of injury.

9. CONCLUSION

The NDCT Rules, 2019 continue to provide clinical trial subjects in India with significant general protection and are a true improvement over the framework they replaced. They do not, however, provide a specific response to the questions that artificial intelligence now raises at every stage of the trial process: who is responsible when an opaque system's output causes harm, whether a participant must be informed that an algorithm shaped their recruitment, and whether the DPDP Act permits the lawful linking and retention of the data needed to train and validate such a system. International data demonstrating inconsistent AI-related disclosure, even in jurisdictions with better developed AI regulation, has led this article to propose that these are active gaps rather than speculative worries. Prior to broader AI adoption in domestic trials, India's regulators have a chance to close this gap through targeted amendment rather than complete redrafting, taking into account the unique capacity limitations of India's ethics committee system while selectively referencing comparative practice. If this isn't done, there's a chance that the very disclosure errors that the 2019 Rules were designed to stop would recur in digital form.

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