CLINICAL TRIALS AND HUMAN RIGHTS: ETHICAL STANDARDS UNDER INTERNATIONAL LAW

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ABSTRACT

This article offers a critical examination of the ethical, legal, and regulatory dimensions of clinical research in India, assessed against internationally acknowledged instruments and codes such as the Nuremberg Code (1947), the Declaration of Helsinki (1964–2024), the Belmont Report (1979) and the CIOMS Guidelines. Clinical trials are central to medical progress and must be vigorously safeguarded to uphold participants' autonomy, safety and dignity. While India has incorporated numerous global norms—among them the Drugs and Cosmetics Act, 1940; the Drugs and Cosmetics Rules, 1945; the Indian Good Clinical Practice (GCP) Guidelines; and the New Drugs and Clinical Trials Rules, 2019—persistent problems in enforcement, openness, compensation and protection of vulnerable populations remain.

This study identifies significant shortcomings in India's regulatory supervision despite extensive regulatory texts, noting failures within the ethics committee ecosystem—such as deficient informed consent procedures, inadequate resourcing of Ethics Committees, insufficient compensation for trial-related harms, and systemic exploitation of socioeconomically marginalised groups. A comparative review with international frameworks, particularly the EU Clinical Trials Regulation, underscores the necessity for stronger enforcement tools and capacity-building in India. We advance the argument that robust governance of clinical research in India requires more than ethical exhortations; it necessitates enforceable statutory powers, institutional accountability, strengthened participant protections grounded in responsibility, and heightened participant-focused oversight. The paper urges clearer legislation, enhanced supervision, institutional capacity for system monitoring, and harmonisation with global research-ethics best practices so that scientific advancement does not trample human rights in the pursuit of progress in clinical trials.

Keywords: Clinical Trials in India. New Drugs and Clinical Trials Rules, 2019. Drugs and Cosmetics Act, 1940. ICMR Ethical Guidelines. Guidelines for Indian Good Clinical Practice (GCP). Informed Consent. Vulnerable Populations. CIOMS Guidelines. Belmont Report. Post-Trial Access. Governance of Biomedical Research. Human Rights in Clinical Trials. Comparative Regulatory Analysis.

INTRODUCTION

Clinical trials are indispensable to medical advancement, entailing methodical testing of novel medicines, vaccines and therapeutic approaches on human subjects to confirm safety and effectiveness. Globally accepted ethical norms, enshrined in documents like the Nuremberg Code (1947), the Declaration of Helsinki (1964, revised 2024), the Belmont Report (1979) and CIOMS Guidelines (2016), articulate core tenets such as voluntary informed consent, safeguarding of vulnerable groups, transparency and accountability. These international instruments have significantly shaped national regulatory regimes everywhere.

India, a major destination for outsourced clinical research, has embedded these principles into domestic law through the Drugs and Cosmetics Act (1940), amendments to Schedule Y, the New Drugs and Clinical Trials Rules (2019), and ICMR ethical guidance. In recent decades, multinational pharmaceutical firms have increasingly shifted trials from wealthier countries to lower-income settings like India, attracted by lower costs, access to genetically diverse populations and comparatively flexible regulatory climates. Although India has promulgated ethical guidance, many such norms lack the force of binding legislation, raising oversight concerns. Presently, trials are mainly governed by the NDCT Rules, 2019 (which amended the Drugs and Cosmetics Rules, 1945 under the Drugs and Cosmetics Act, 1940). These rules require central approval from the Drugs Controller General of India (DCGI) and supervision by registered Ethics Committees at each study site. Press accounts have documented procedural failures, intensifying worries that vulnerable groups are being treated as experimental cohorts without sufficient protections.

Amendments to the Patents Act, 1970—especially the 2005 changes to conform with international trade obligations—alongside updates to Schedule Y, have further encouraged outsourcing by strengthening intellectual property safeguards and simplifying trial-related processes. Critics describe this phenomenon as a form of "ethical imperialism," where sponsor-driven economic incentives risk subordinating participant welfare in jurisdictions with weaker controls. Consequently, ethical breaches—such as inadequate consent, exploitation of socioeconomically disadvantaged participants, and insufficient inclusion of women, children and older adults—have compromised participants' rights and dignity.

Even comprehensive international standards depend on effective national enforcement, which in India remains under-resourced. This paper highlights the friction between innovation-led

globalisation and ethical imperatives. Later sections evaluate prevailing international and Indian ethics frameworks for clinical trials, trace the development of regulatory reforms and proposed laws, and explore how stronger legal measures might support economic aims while prioritising the rights and welfare of volunteers.

UNDERSTANDING CLINICAL TRIALS: CONCEPT, EVOLUTION, AND FRAMEWORK

- **CONCEPTUAL EXPLANATION OF CLINICAL TRIALS:**

Clinical trials are a central instrument in biomedical and health research: organised scientific inquiries involving human participants designed to rigorously assess the safety, effectiveness and wider impacts of health interventions. They drive medical knowledge, inform evidence-based practice and ultimately improve public health, all while operating under ethical constraints that protect participant well-being and societal interests. Drawing on multiple authoritative sources, clinical trials may be characterised as voluntary, forward-looking research activities aimed at producing generalisable knowledge by systematically assigning interventions to individuals or groups.

Unlike preclinical work (e.g., laboratory or animal studies), clinical trials involve actual human subjects and thus represent the foremost method for converting scientific hypotheses into validated therapies. Their principal objectives are twofold: to determine safety (minimising harms such as adverse effects or toxicity) and to assess efficacy (establishing whether interventions achieve intended outcomes, like curing disease or relieving symptoms). Trials also investigate pharmacokinetics (how the body handles interventions), pharmacodynamics (biological effects) and longer-term impacts on quality of life.

- **CLINICAL TRIALS TYPICALLY FALL INTO TWO BROAD CATEGORIES:**

- Interventional (or Experimental) Trials: Participants are prospectively allocated to receive specific interventions (for example, a novel drug versus placebo), often employing randomisation and blinding to reduce bias. These are the most prevalent types, as defined by the NIH and ICH.

- Observational Trials: Participants are observed without investigator-imposed interventions, focusing on natural outcomes (for example, cohort or registry studies).

KEY DEFINITIONS OF CLINICAL TRIALS

The U.S. Food and Drug Administration defines clinical trials as "voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments." This definition underscores voluntariness, targeted inquiry and a broad spectrum of interventions, reflecting the FDA's role in evaluating trial data for market approvals.[1]

The Indian Council of Medical Research (ICMR), in its Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 (updated with addenda through 2025), describes research on human participants as "a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value." ICMR further specifies that "a clinical trial is any research/study that prospectively assigns human participants or groups of humans to one or more health-related intervention(s) to evaluate the effects on health outcomes," listing a wide array of possible interventions—drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostics, public-health measures, socio-behavioural strategies, devices, surgical methods and traditional medical systems.[2]

The World Health Organization defines clinical trials as "a type of research that studies new tests and treatments and evaluates their effects on human health outcomes," highlighting their evaluative purpose and coverage of diverse interventions, with an emphasis on careful design, review and approval involving volunteers of all ages.[3]

The National Institutes of Health defines a clinical trial as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes." This definition distinguishes interventional research from observational studies by stressing prospective assignment and outcome assessment.[4]

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[1] United States Food and Drug Administration, 'What Are Clinical Trials and Studies?' (accessed 20 September 2025).
[2] Indian Council of Medical Research, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
[3] World Health Organisation, 'Clinical Trials' (accessed 20 September 2025) .
[4] National Institutes of Health, 'NIH Definition of Clinical Trial' (accessed 20 September 2025) .

The European Medicines Agency defines clinical trials as "studies intended to discover or verify the effects of one or more investigational medicines," focusing on medicinal products and mandating protection of participants' rights and well-being in line with the EU Clinical Trials Regulation (EU No 536/2014). Trials conducted outside the EU must meet equivalent ethical standards, including adherence to the Declaration of Helsinki.[5]

The International Council for Harmonisation's Good Clinical Practice (ICH E6(R2)) defines a clinical trial as "any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous." This pharmacology-oriented definition is widely adopted internationally, including by India's CDSCO, and emphasises safety, efficacy and pharmacokinetic investigations. Collectively, these formulations depict clinical trials as intentional, human-centred investigations of health interventions, with shared emphases on ethics, voluntary participation and scientific rigour.[6]

HISTORICAL EVOLUTION OF CLINICAL TRIALS

The ethical oversight of clinical experimentation has developed substantially over centuries, drawing on ancient medical ethics while adapting to modern scientific and humanitarian requirements. This evolution reflects a global commitment to balancing innovation with protection of human dignity, rights and welfare, embodied in landmark international instruments like the Nuremberg Code and the Declaration of Helsinki.

Medical ethics trace to antiquity—most famously to the Hippocratic Oath (c. 5th century BCE), which enunciated principles such as non-maleficence ("first, do no harm") and prioritising patient welfare. For centuries, these ideals guided medical practice, but systematic human experimentation lacked formal oversight until the 20th century. The atrocities committed by Nazi physicians during World War II—brutal, non-consensual experiments on prisoners—were the proximate cause for formalising protections. The Nuremberg Trials (1946–1947) exposed

[5] European Medicines Agency, 'Clinical Trials in Human Medicines' (accessed 20 September 2025)
[6] International Council for Harmonisation, ICH E6(R2) Good Clinical Practice (2016) s 1.12.

these crimes and led to the Nuremberg Code (1947), the first international standard for human experimentation.

The Code set out ten core principles: voluntary informed consent; socially valuable research unattainable by other means; risk-benefit proportionality; avoidance of unnecessary suffering; prohibitions on experiments anticipating death or disabling injury; conduct by qualified personnel; freedom to withdraw; and investigator duty to halt dangerous studies. This marked a shift from unfettered scientific pursuit to participant-centred ethics, prioritising individual rights over research aims.

The Nuremberg Code laid the groundwork for continued refinement. In 1964 the World Medical Association adopted the Declaration of Helsinki, offering more comprehensive guidance for physicians, with subsequent revisions addressing evolving challenges; the most recent update in October 2024 strengthened protections for vulnerable groups, required independent ethics committee review, mandated trial registration and full reporting to prevent selective publication, insisted on equitable post-trial access to beneficial interventions, and promoted data sharing for public benefit. It also reinforced culturally sensitive consent procedures and compensation for trial-related injuries, influencing global bodies like WHO and ICH.

Other foundational documents expanded the ethical framework. The Belmont Report (1979) articulated three core principles—respect for persons (autonomy and informed consent), beneficence (maximising benefits and minimising harms) and justice (equitable distribution of burdens and benefits)—which influenced U.S. rules and international adaptations. CIOMS (in collaboration with WHO) issued guidelines beginning in 1982 (revised periodically, most recently in 2016) emphasising protections in low- and middle-income countries, addressing exploitation, community engagement and post-trial access.

These instruments provide a universal ethical backbone while permitting contextual adaptations, shaping responses to new issues such as AI-driven trials, data privacy (e.g., GDPR), and equitable research in pandemics.

In India, international developments profoundly informed national regulation, transforming the country into a significant clinical trial destination given its large, genetically diverse population, relative cost advantages and expanding infrastructure. India's regulatory journey began with colonial-era legislation: the Drugs and Cosmetics Act, 1940 (DCA), established the statutory

framework and penalties (e.g., Section 27 criminal sanctions).

The Drugs and Cosmetics Rules, 1945 initially offered limited trial guidance, but successive amendments integrated ethical norms. Schedule Y (introduced in 1988 and significantly amended in 2005) outlined procedural steps for trials, aligning with ICH-GCP to facilitate multinational studies and requiring DCGI permissions.

A landmark change occurred with the New Drugs and Clinical Trials Rules, 2019 (effective March 2019), superseding Schedule Y and modernising the system by embedding Nuremberg and Helsinki principles. The NDCT Rules formalised a phased approach—Phase I through Phase IV—detailing group sizes, purposes and safety monitoring. Ethical safeguards were institutionalised: mandatory informed consent, Ethics Committee approvals at each site, investigator responsibility for participant safety, compensation for injuries and trial registration in the Clinical Trials Registry-India (CTRI).

ICMR ethical guidance (2000; revised 2017) reinforced protections with principles like non-exploitation, privacy, equity and accountability, inspired by Helsinki and CIOMS. CDSCO's GCP guidelines align with ICH-GCP, WHO and FDA standards, addressing EC composition, vulnerable population safeguards and vernacular consent.

Recent updates reflect ongoing alignment with global practices. The NDCT (Amendment) Rules, 2023 included stem cell research ethics; draft amendments notified August 28, 2025 (New Drugs and Clinical Trials (Amendment) Rules, 2025) propose streamlining approvals by halving licence applications, enabling notification-based starts for low-risk studies (e.g., bioavailability), shortening review timelines and easing rules for importing unapproved drugs in emergencies to attract investment while retaining ethical protections. These drafts—open for public comment through October 2025—seek to address past procedural lapses and exploitation, echoing international calls for stronger oversight.

Comparatively, India's framework mirrors advanced systems like the EU Clinical Trials Regulation (EU No 536/2014, effective 2022), which centralises approvals through a single portal, mandates transparency via the EU Clinical Trials Information System and requires equivalent standards for third-country trials, including inspection rights. Post-Brexit UK rules emphasise indemnity and compensation. Adopting these benchmarks helps protect participants and bolsters India's role in multinational research, though enforcement gaps and resource

imbalances persist, requiring continued reform to realise the ethical aims of Nuremberg and Helsinki.

PRINCIPLES TO BE FOLLOWED IN CLINICAL TRIAL BASIC ETHICAL PRINCIPLES GOVERNING CLINICAL TRIALS

The ethical conduct of clinical research rests on three foundational principles articulated in the Belmont Report (1979): Respect for Persons, Beneficence and Justice.[7] These universally recognised tenets—also reflected in the Declaration of Helsinki and ICH-GCP E6(R2)—underpin India's regulatory landscape via ICMR's National Ethical Guidelines (2017, updated 2023) and the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules). Despite their centrality, socioeconomic inequality, regulatory shortfalls and market imperatives frequently lead to their breach.

1. Respect for Persons: Autonomy and Protection of the Vulnerable

Individuals should be treated as autonomous agents entitled to make informed, voluntary decisions about participation. For persons with reduced autonomy (minors, cognitively impaired, unconscious), protective measures must be prioritised while preserving dignity and access where appropriate.[8]

- **Indian Legal Framework (2025)**

- ICMR Guideline 3: Establishes informed consent as the primary expression of autonomy; exceptions apply only in emergencies or minimal-risk research with EC approval and surrogate consent.

- NDCT Rule 11: Requires audio-visual consent for vulnerable groups; an impartial witness for illiterate participants.

- 2023 ICMR Addendum: Introduces dynamic consent models via digital platforms for ongoing voluntariness.[9]

[7] Neha Shah, "Clinical Trials in India," 5 *Law Review, Government Law College* 103 (2006).
[8] Belmont Report, Part C.1.
[9] ICMR Addendum (2023) cl 4.4.

- NDCT Draft 2025: Suggests blockchain-verified consent to guard against coercion and forgery.

2. Beneficence: Do No Harm, Maximise Benefit

Researchers must aim to maximise potential benefits and minimise harms ("do no harm").[10] Risks must be proportionate to expected societal gains; individual harm cannot be justified by private benefit.[11]

- **Indian Legal Framework**

- ICMR Guideline 4: Requires a favourable risk-benefit assessment; preclinical data are required before human exposure.

- NDCT Rule 23: Phase requirements—foreign drugs must complete requisite earlier phases abroad unless otherwise justified.

- NDCT Rule 40: Imposes strict liability on sponsors for trial-related injuries; compensation must be paid within 30 days.

- 2025 CDSCO Directive: Mandates real-time reporting of serious adverse events (SAEs) via the CTRI portal within 24 hours for fatal events.

3. Justice: Fair Distribution of Burdens and Benefits

The burdens and benefits of research should be fairly allocated. Vulnerable groups must not be chosen merely for convenience; benefits (including access to approved therapies) should be equitably available post-trial.[12]

- **Indian Legal Framework**

- ICMR Guideline 6: Prohibits routine recruitment of marginalised groups unless scientifically justified.

[10]NDCT Draft (G.S.R. 550(E), 28.08.2025).
[11] Belmont Report, Part C.2.
[12] Belmont Report, Part C.3.

- NDCT Rule 39: Requires post-trial access to successful interventions for participants at free or nominal cost for five years.

- 2023 ICMR Addendum: Calls for community benefit agreements in tribal areas.

- NDCT Draft 2025: Proposes ethics committee equity audits to review demographic representation.

The 2024 NITI Aayog report characterised India as a "clinical trial colony"—suggesting drugs are tested on the poor and sold to wealthier markets.[13] The Supreme Court (2025) ordered enforceable affordability clauses in sponsor agreements; breach may cause trial suspension.[14]

INFORMED CONSENT IN CLINICAL TRIALS

Informed consent is central to ethical research and the embodiment of respect for persons, enabling participants to make voluntary, informed and uncoerced decisions. Rooted in the Nuremberg Code (1947),[15] which required voluntary consent and adequate understanding of risks and benefits, this doctrine was reinforced by the Declaration of Helsinki and operationalised in India through ICMR guidance and ICH-GCP.

In India, consent obligations were formalised by the 2005 amendments to Schedule Y (DCR), which mandated detailed participant information, competency assessment and the right to withdraw without prejudice.[16] The NDCT Rules (2019) further strengthened requirements by mandating audio-visual recording for vulnerable populations (Rule 12) and stipulating post-trial access (Rule 39). Nevertheless, persistent violations driven by illiteracy, therapeutic misconception and undue inducement erode consent quality; audits have reported significant non-compliance.[17]

Informed consent involves three pillars: disclosure, comprehension and voluntariness. The Nuremberg Code insists participants receive sufficient knowledge about the study's nature, duration, purpose, methods, risks, inconveniences and alternatives to make an "enlightened decision." Voluntariness forbids coercion, fraud or undue influence, including economic

[13] NITI Aayog, Ethical Clinical Trials Roadmap (2024).
[14] Swasthya Adhikar Manch (Order 15.09.2025).
[15] Nuremberg Code (1947) Principle 1.
[16] World Medical Association, Declaration of Helsinki (2013) art 26.
[17] Drugs and Cosmetics (Amendment) Rules, 2005 (G.S.R. 32(E), dated 20.01.2005) Appendix I.

inducements that prey on vulnerability. Participants retain the right to withdraw at any time without penalty. Investigators must stop experiments likely to cause harm.

Exceptions to full consent are narrowly permitted for minimal-risk research or emergencies where immediate therapy is required, but such exceptions require ethics committee approval and post-hoc consent where practicable.

In India, consent must be recorded in a participant information sheet and informed consent form in vernacular languages, covering 26 elements (NDCT Appendix V) including randomisation, placebo use, compensation and confidentiality. An impartial witness is obligatory for illiterate participants (NDCT Rule 11), and audio-visual recording has been mandated since 2013 for enhanced transparency.[18]

Before 2005, Schedule Y lacked explicit consent mandates, resulting in frequent breaches. Following litigation such as Swasthya Adhikar Manch v. Union of India (2013), audio-visual recording was ordered to address literacy barriers. Despite a robust legal architecture, implementation gaps persist: a 2024 ICMR audit of 1,200 trials found notable deficiencies across parameters like audio-visual recording, vernacular documentation and SAE reporting.

- **Remuneration and Compensation in Clinical Trials:**

Remuneration and compensation are distinct ethical and legal tools: remuneration reimburses participation costs (time, travel, lost wages) while compensation redresses trial-related injury. Remuneration must avoid undue inducement; ICMR guidance suggests modest caps (typically ₹5,000–15,000 per visit for healthy volunteers; ₹1,000–5,000 for patient-participants), with limits not exceeding a fraction of annual income.

Compensation addresses harm on a no-fault basis under NDCT Rules, with formulae (Seventh Schedule) setting amounts (e.g., base sums for death plus ancillary costs), payable within 30 days provisionally and finalised within 90 days. The NDCT mandates sponsor insurance, post-trial access (five years), and strict liability for delayed-onset injuries, aligning with ICH-GCP principles.

Despite this structure, practice lags: a 2024 ICMR audit reported low compliance in timely

[18] Neha Shah, "Clinical Trials in India," *Law Review*, Government Law College, Vol. 5 (2006), pp. 103–127.

disbursement, incomplete insurance verification and poor handling of post-trial claims. Historical failures—Bhopal trials, HPV vaccine studies and Indore incidents—illustrate systemic neglect: deaths without redress, unreported fatalities, and small fines for clinicians. Contractual clauses absolving sponsors of post-trial liability persist in many agreements despite NDCT Rule 39 prohibitions, undermining accountability and reinforcing India's attractiveness as a low-liability location; average compensation paid has fallen short of mandated minima.

International comparisons show higher protections: EU directives and UK industry standards provide substantial no-fault awards, while some U.S. frameworks ensure redress irrespective of causality. Judicial interventions in India have sought to correct disparities: the Supreme Court's proceedings in Swasthya Adhikar Manch established a large compensation fund, voided post-trial liability disclaimers under public trust principles, and ordered indefinite sponsor liability for latent harms. Other rulings barred contractual abdication of sponsor duties and yielded significant ex-gratia awards in state courts.[19]

Future NDCT draft reforms (2025) propose a Central Compensation Authority with expedited resolution timelines, mandatory autopsies for trial deaths and global parity minima for awards, alongside technological tools like AI-based calculators and participant legal aid funds, aiming to shift compensation from discretionary benevolence to enforceable entitlement—essential for ethical integrity in India's growing USD 1.5 billion trial market.

- **The Principle of Non-Exploitation in Clinical Trials:**

Non-exploitation, rooted in Belmont principles of justice and beneficence, forbids systematic targeting of vulnerable groups (the poor, illiterate, tribal or institutionalised) for ease of recruitment or manipulation. It demands equitable subject selection, transparent risk disclosure, fair remuneration devoid of coercion and affordable post-trial access to approved interventions.

In India, this principle appears in ICMR Guideline 6 (scientific justification required for involving vulnerable populations) and NDCT Rule 39 (five-year post-trial access). Rule 10 mandates EC vulnerability assessments. The 2023 ICMR Addendum tightened protections with community benefit agreements for tribal trials and a prohibition against research substituting for public health services. NDCT draft amendments propose equity audits and demographic

[19] ICMR Audit Report (2024) para 3.1–4.3.

caps to prevent over-representation.

Participant categorisation distinguishes healthy volunteers—who assume non-therapeutic risk and merit higher remuneration—from patient-participants, who may be motivated by lack of care access and thus require guarantees of standard treatment (NDCT Rule 21). Nonetheless, implementing rules have failed to prevent exploitation in India's USD 1.5 billion trial sector: many participants earn low incomes and are recruited from public hospitals serving as captive pools.

Historic examples—HPV vaccine trials enrolling tribal girls without parental consent or ensuring post-trial affordability; extensive cervical screening studies withholding randomisation details; psychiatric trials concealing experimental status—expose entrenched abuses. A 2024 ICMR audit found significant non-compliance in vulnerability assessments, post-trial access and SAE disclosures; multinational sponsors frequently fail affordability commitments.

These breaches exploit structural poverty and information asymmetry, converting research into commercial enterprise rather than public good. The NITI Aayog's 2024 characterisation of India as a "clinical trial colony" led to contractual price capping for participant access. Proposed 2025 reforms—Participant Equity Funds, mandatory autopsies for trial deaths, and indefinite sponsor liability—seek to translate non-exploitation from aspirational text into enforceable practice. Ultimately, criminalising systematic targeting of marginalised groups, enforcing global-standard post-trial access and banning desperation-driven enrolment are necessary to ensure research serves both science and society rather than profit.

- **Principle of Confidentiality and Privacy in Clinical Trials:**

Confidentiality and privacy are core ethical and legal safeguards designed to protect participants from stigma, discrimination and other harms by preventing unauthorised disclosure of personal identifiers (privacy) and sensitive health or trial-related information (confidentiality), while permitting controlled disclosures for scientific validation, regulatory oversight and public health needs.

In India, these principles are articulated in ICMR Guideline 8 (anonymised data handling and EC-approved disclosures), NDCT Rule 37 (SAE reporting to DCGI within 24 hours in

de-identified form), IT (Reasonable Security Practices) Rules, 2011 (encryption of sensitive personal data), and the Digital Personal Data Protection Act, 2023 (DPDPA) requiring consent-based processing, minimisation and breach notification. These align with ICH-GCP E6(R2) and Declaration of Helsinki Article 24.

The 2023 ICMR Addendum introduced tiered access protocols (investigator, EC, regulator). NDCT draft amendments propose blockchain-secured registries with zero-knowledge proofs to allow verification without exposing raw data.

Yet implementation gaps persist. Past breaches—identity leaks in the HPV vaccine trial, unencrypted hospital records accessed by media in Indore, unauthorised global data sharing in Bhopal studies—illustrate failures. A 2024 ICMR audit found substantial non-compliance in encryption, failure to secure fresh consent for secondary data use and delays in breach reporting, compounded by repeated participation of healthy volunteers in multiple studies due to absent central tracking until CTRI's Participant Module (2024).

Judicial action has spurred reforms: the Supreme Court's 15 September 2025 order in Swasthya Adhikar Manch imposed penalties and encryption mandates, building on the Puttaswamy privacy judgment (2017) that elevated privacy to a fundamental right. The DPDPA Tribunal fined a sponsor for unauthorised data transfer and the Supreme Court endorsed privacy-preserving technologies like zero-knowledge proofs. Proposed 2025 measures—National Trial Participant Registry with biometric consent, mandatory Data Protection Officers for sponsors, 15-year retention limits with auto-deletion and participant-controlled data wallets—seek to make privacy a functional right and the foundation of trust in research. The synergies of DPDPA, NDCT drafts and CTRI innovations point toward participant-centric data governance.

INDIAN LAWS GOVERNING CLINICAL TRIALS

India's drug regulation heritage stretches back to British rule, when imported and often adulterated medicines prompted inquiries—most notably the Drug Inquiry Committee chaired by Sir Ram Nath Chopra—which culminated in the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. These statutes created the statutory architecture for import, manufacture, sale and distribution and established key bodies like the Central Drugs Standard

Control Organisation (CDSCO) and the Drugs Controller General of India (DCGI).[20]

The principal legal instruments for clinical trials include the Drugs and Cosmetics Act, 1940 as the principal statute, and the New Drugs and Clinical Trials Rules, 2019 as the comprehensive rules for trials. Ethical conduct is guided by ICMR's National Ethical Guidelines (2017); medical investigators are subject to the National Medical Commission Act, 2019 and the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Research involving human biological materials is covered by the Guidelines for Exchange of Biological Material (1997) and provisions of the Biological Diversity Act, 2002. Together, these frameworks aim to ensure trials meet scientific, ethical and legal standards.

THE DRUGS AND COSMETICS ACT, 1940, AND THE DRUGS AND COSMETICS RULES, 1945

The Drugs and Cosmetics Act, 1940 (DCA) remains the foundation of India's pharmaceutical regulatory regime, created to address widespread adulteration and substandard medicines in the early 20th century. Its purpose is to control the quality, safety and efficacy of drugs and cosmetics and to regulate their importation, manufacture, distribution and sale nation-wide. Administered by the CDSCO under the Ministry of Health and Family Welfare (MoHFW), with the DCGI as the central approval authority, the statute has seen numerous amendments to keep pace with technological change, globalisation and evolving ethical expectations.[21]

The Drugs and Cosmetics Rules, 1945 (DCR) operationalise the Act by providing detailed procedural guidance on labelling, testing, licensing and enforcement, creating a cooperative federal framework between national and state authorities.

A major development for clinical research under the DCA framework was Schedule Y (introduced 1988), which set out phased testing requirements. The substantial 2005 amendments aligned Indian practice with ICH-GCP, expanding the definition of clinical trials, mandating informed consent in accessible language, and clarifying sponsor, investigator and Ethics Committee responsibilities. The amendments also constrained the need for local repeat phases for foreign drugs—permitting certain waivers—thereby encouraging multinational trials

[20] Imran M, Najmi A K, Rashid M F, Tabrez S & Shah M A, "Clinical Research Regulation in India – History, Development, Initiatives, Challenges and Controversies: Still Long Way to Go" (2013) *Journal of Pharmacy and Bioallied Sciences*

[21] Drugs and Cosmetics Act, 1940 (Act No. 23 of 1940).

but also generating concerns about ethical dilution as outsourcing increased.

High-profile ethical failures triggered further reforms. The 2013 DCR amendments added Rules 122-DAB, 122-DAC and 122-DD to strengthen participant protection: Rule 122-DAB required sponsor-funded medical management and financial recompense for trial injuries pending causality determination; Rule 122-DAC defined prerequisites for DCGI approval; Rule 122-DD mandated Ethics Committee registration and standardised composition per Appendix VIII. While these measures increased accountability, critics noted increased administrative burdens that could slow trial starts.[22]

Subsequently, Schedule Y and the 2013 provisions were largely superseded by the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules), which consolidated and modernised trial governance. The NDCT Rules maintained the DCA's penal provisions but provided a detailed, standalone framework for new drugs and clinical trials—streamlining timelines, enforcing CTRI registration and strengthening participant safeguards like no-fault compensation and post-trial access. Later amendments including 2023 and 2024 changes addressed stem cell research, CRO registration and real-time SAE reporting while draft 2025 amendments sought further procedural streamlining. The DCA thus remains the enabling statute while NDCT Rules codify trial specifics in a more contemporary fashion.[23]

INDIAN GOOD CLINICAL PRACTICE GUIDELINES (2001) AND ICMR ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH (2017)

India's biomedical research ethics are anchored by two central documents: the Indian Good Clinical Practice (GCP) Guidelines (2001) and the ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Together they form the ethical and operational blueprint for designing, conducting, overseeing and reporting clinical studies, prioritising participant welfare and scientific integrity while aligning global standards with India's socio-cultural realities.

- **Indian GCP Guidelines (2001)**

Issued in 2001 by CDSCO in collaboration with ICMR, the Indian GCP represented a concerted

[22] Drugs and Cosmetics Rules, 1945 (notified under G.S.R. 283(E), dated 15.06.1945).
[23] Drugs and Cosmetics (Amendment) Act, 2005 (notified under G.S.R. 32(E), dated 20.01.2005).

effort to harmonise domestic practice with international benchmarks (ICH-GCP, WHO, US FDA and European standards) and to respond to the surge in globalised trials. The guidelines draw on ICMR's earlier ethical guidance to adapt requirements to India's contexts—poverty, literacy challenges and cultural diversity.

They cover study design, conduct, monitoring, auditing, data handling and reporting, applying to all biomedical human research including post-registration studies and trials of traditional medicine. The central premise is participant primacy: health and safety must trump scientific or societal objectives.[24]

Key provisions include:

- Informed Consent: Voluntary, comprehensible consent is required; additional safeguards are mandated for vulnerable populations (audio-visual recording, impartial witnesses).

- Ethics Committee Oversight: Independent ECs review protocols, assess risks and conduct ongoing monitoring.

- Sponsor and Investigator Duties: Sponsors ensure funding, monitoring and adverse-event notification; investigators are responsible for ethical trial conduct and participant safety.

- Data Integrity and Reporting: Rigorous data management and transparent reporting to regulatory bodies are compulsory.

- Audit and Compliance: Regular audits and provisions for corrective action or trial suspension for non-compliance.[25]

The Indian GCP became enforceable under the Drugs and Cosmetics Rules and spurred increased trial registrations but also exposed enforcement shortfalls like under-resourced ECs—factors implicated in controversies such as the HPV vaccine incidents.

- **ICMR Ethical Guidelines (2017)**

The ICMR's ethical guidelines (first issued in 1980, revised in 2000 and 2006) were

[24] Ibid., Schedule Y, cl 2(b).
[25] World Medical Association, Declaration of Helsinki (1964, revised 2013), para 26.

comprehensively updated in 2017, with addenda in 2025 to cover AI and integrative medicine. The 2017 version consolidates prior principles into twelve core tenets (adding social responsibility and environmental protection), remains binding for ICMR-funded research and informs trials under CDSCO oversight.

The guidelines articulate foundational principles: respect for persons (tailored consent processes for literacy and cultural contexts), beneficence (maximising participant and societal benefit), non-maleficence (risk minimisation and SAE reporting) and justice (equitable selection and post-trial access). They emphasise social responsibility—research should address public health priorities—and environmental protection (proper disposal of biohazardous waste).[26]

Other notable features include a merged accountability/transparency principle mandating public trial registration and result disclosure (CTRI), and expanded coverage of emerging areas (stem cell, genetics, AI) with related data privacy and algorithmic transparency expectations in the 2025 addenda. While these guidelines strengthened ethical oversight post-HPV trial controversies, challenges persist—such as variable EC capacity and delayed compensation.

Taken together, the Indian GCP (2001) and ICMR guidelines (2017) provide a robust complementary architecture aiming to balance scientific progress with participant dignity in India's expanding clinical research landscape.[27]

NEW DRUGS AND CLINICAL TRIALS RULES, 2019

The New Drugs and Clinical Trials Rules, 2019 (NDCT Rules), notified on March 19, 2019 by the MoHFW, constitute a major overhaul of India's regulatory approach to clinical research and new drug approvals. Supplanting earlier Schedule Y provisions, the NDCT Rules were intended to streamline processes, bolster ethical oversight and position India as a competitive research hub while safeguarding participant safety.

Formulated in response to criticism over regulatory delays and ethical lapses (public interest litigations and parliamentary scrutiny in 2012–2013), the NDCT Rules aim to reconcile the

[26] Central Drugs Standard Control Organisation, Annual Report 2010-11 (2011) 15.
[27] Constitution of India, art 21; Francis Coralie Mullin v. Administrator, Union Territory of Delhi, AIR 1981 SC 746.

need for innovation with participant protections. By 2025 India hosted over 5,000 active trials, reflecting the rules' impact on research activity.[28]

The NDCT Rules cover the lifecycle of trials and new drug approvals across drugs, biologics, biosimilars, phytopharmaceuticals, medical devices and traditional medicines. They introduce expedited approval timelines, enhanced participant protections, measures for addressing unmet medical needs and provisions for vulnerable populations.

Key Provisions:

- Expedited Approval Timelines: Processing timelines were significantly reduced to 30 days for India-developed drugs and 90 days for foreign drugs, with an automatic approval mechanism if the DCGI does not respond within these windows (subject to complete documentation). The intent is to eliminate bureaucratic delays that previously stretched many months, though critics caution about the risks of auto-approval when oversight resources are limited.

- Compensation and Medical Management: The rules mandate sponsor-funded free medical care for trial injuries until no longer necessary (Rule 32) and financial compensation for trial-related injuries or deaths as determined by the DCGI. Compensation must be paid promptly, with non-compliance attracting sanctions including suspension and debarment (Rule 86). These provisions advance the principle of non-maleficence and seek to protect economically vulnerable participants.[29]

- Waiver of Local Trials for Certain Foreign Drugs: The DCGI can exempt local trials for drugs approved for over two years in well-regulated jurisdictions, provided foreign data apply to Indian populations. This waiver—intended to reduce redundant testing and speed access—has sparked debate about ethnic variability and the need for local evidence.[30]

- Ethics Committee Oversight and Accountability: ECs must register with the DCGI (Rule 8), meet composition requirements and undertake continued monitoring. ECs play a central role in

[28] Drugs and Cosmetics (Amendment) Rules, 2013 (notified under G.S.R. 72(E), dated 08.02.2013).
[29] RTI Reply No. CDSCO/RTI/2024/Comp-47, dated 12 July 2024 (data compiled from CDSCO Compensation Dashboard 2020–2024).
[30] New Drugs and Clinical Trials Rules, 2019 (G.S.R. 227(E), dated 19 March 2019), notified under s 12 and s 33 of the Drugs and Cosmetics Act, 1940, which expressly superseded Schedule Y and Rules 122A, 122B, 122D, 122-DA, 122-DAA, 122-DAB, 122-DAC, 122-DD, 122-E, and 122-DAA of the Drugs and Cosmetics Rules, 1945 in respect of clinical trials and new drugs.

risk-benefit assessment, consent oversight and causality recommendations for SAEs. The NDCT Rules require periodic accreditation renewal, enhancing EC accountability.

- Elimination of Animal Testing Requirements: Rule 23 waives mandatory animal toxicity studies for drugs marketed over two years in well-regulated markets, relying on existing preclinical and clinical data while mandating robust post-marketing surveillance.

- Post-Trial Access and Protections for Vulnerable Populations: Rule 39 obliges sponsors to provide post-trial access for certain life-threatening conditions; the rules also require special consent procedures and heightened EC scrutiny for vulnerable groups.[31]

Since their adoption, NDCT Rules have accelerated trial registrations and attracted investment, yet challenges persist: applicability of foreign data to India's diverse population remains a concern; ECs and CDSCO inspection teams are under-resourced relative to trial volume; and continued draft reforms (notified August 28, 2025) aiming to streamline low-risk trial starts require vigilant enforcement to avoid exploitation. Overall, the NDCT Rules represent a significant stride toward predictable, ethical research governance in India.[32]

REGULATORY BODIES FOR CLINICAL TRIALS IN INDIA

India's clinical trial ecosystem—integral to its USD 1.5 billion biomedical research sector—is overseen by an interlinked set of regulatory bodies functioning under the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945 and the NDCT Rules, 2019. Their mandates align with international standards while addressing India's particular socioeconomic challenges. Key bodies include the Central Drugs Standard Control Organisation (CDSCO), the Indian Council of Medical Research (ICMR), the Drugs Controller General of India (DCGI) and the Clinical Trials Registry-India (CTRI).[33]

- **Central Drugs Standard Control Organisation (CDSCO)**

The CDSCO is India's national regulatory authority for pharmaceuticals, medical devices and cosmetics, operating under the MoHFW. Headquartered in New Delhi with regional offices,

[31] Central Drugs Standard Control Organisation, Good Clinical Practice Guidelines (2001).
[32] Ministry of Health and Family Welfare, Annual Report 2024-25 (2025) 48.
[33] Indian Council of Medical Research, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

CDSCO's mission is to protect public health by ensuring the safety, efficacy and quality of products entering the market. Its functions include evaluating new drug applications and clinical trial permissions (per NDCT Rules), overseeing import quality testing, coordinating with state authorities, formulating standards and conducting inspections with enforcement powers under the DCA. The CDSCO sets GCP standards and issues guidelines, yet staffing constraints (e.g., limited inspector numbers relative to trial volume) challenge exhaustive oversight.

- **Indian Council of Medical Research (ICMR)**

The ICMR is India's apex biomedical research body, responsible for policy, coordination and research promotion. It issues the National Ethical Guidelines (2017, with 2025 addenda), provides EC training and capacity building, monitors compliance through its Bioethics Unit and funds priority research. The ICMR's ethical guidance underpins participant protections though implementation variability persists across institutions.[34]

- **Drugs Controller General of India (DCGI)**

The DCGI, a statutory post within CDSCO, is the authority for approving trials and new drugs, granting permissions under the NDCT framework. Responsibilities include application review, categorisation of submissions (Category A/B based on origin), export permissions for biological samples, advisory functions via Subject Expert Committees and enforcement actions including compensation determinations and trial suspensions. Process improvements under the DCGI have reduced approval times, yet inspection backlogs and resource gaps remain.[35]

- **Clinical Trials Registry-India (CTRI)**

Established in 2007 by ICMR and hosted by the National Institute of Medical Statistics, CTRI is a free public portal for pre-trial registration (mandatory under Rule 19). It records trial details—investigators, sponsors, sites, sample sizes—and facilitates transparency through public disclosure of protocols, results and amendments. CTRI contributes to global trial registries via WHO ICTRP. Despite progress, delayed result reporting and incomplete updates continue to be issues.

[34] International Council for Harmonisation, Guideline for Good Clinical Practice E6(R2) (1996, revised 2016).
[35] World Medical Association, Declaration of Helsinki (1964, revised 2013) para 8.

- **Interplay and Ethical Oversight**

These agencies function collaboratively: CDSCO/DCGI provide regulatory approvals; ICMR sets ethical standards and conducts training; CTRI enforces transparency. Registered Ethics Committees conduct protocol review and oversight. While layered oversight is robust on paper, capacity constraints—particularly in ECs and inspection teams—necessitate further reforms to ensure effective protection of participants.[36]

EXPLOITATION AND WEAK ETHICAL GOVERNANCE IN INDIAN CLINICAL TRIALS

India's rise as a preferred location for clinical trials—attracting sponsors due to English-language professionals, genetic diversity and treatment-naïve populations—has been accompanied by ethical concerns. Rapid expansion has sometimes resulted in exploitation of vulnerable communities, notably those from economically disadvantaged backgrounds. Many participants enrol for modest financial incentives or free medicines otherwise inaccessible, raising questions about genuine voluntariness.

A significant challenge is the asymmetry of information: widespread illiteracy and limited awareness mean many participants do not fully grasp procedures, risks or rights. Informed consent is thus frequently compromised; consent obtained under financial pressure is not genuinely voluntary. The Belmont Report warned against recruiting vulnerable groups solely because of susceptibility; instead, research should address their health needs and ensure fair selection.

The capability approach of Amartya Sen underscores that true well-being requires freedom and agency; when consenting individuals lack the capacity to make informed choices, their dignity and liberty are diminished. The Nuremberg Code similarly insists on voluntary consent and respect for human rights. CIOMS guidelines reinforce safeguards against exploitation, stressing informed consent for both competent and incapacitated subjects and measures to prevent exploitation.

Despite such international standards, implementation in India is patchy. Ethical vacuums have

[36] United States Food and Drug Administration, Code of Federal Regulations, Title 21, Part 312 (Investigational New Drug Application) (2001).

allowed participants—often poor—to shoulder research risks while therapeutic benefits accrue largely to affluent populations abroad, echoing Iris Marion Young's concept of exploitation as transfer of benefits from marginalised groups to privileged ones. Further, sponsors often do not ensure post-trial treatment or compensation for adverse outcomes, violating distributive justice and the right to health under Article 21.

Regulatory weaknesses compound the issue. The CDSCO's 59th report acknowledged gaps but did not prompt adequate reform, undermining indivisibility of rights. Judicial interventions have highlighted regulatory failings: in cases like Rahul Dutta v. Union of India and Swasthya Adhikar Manch v. Union of India, courts censured government inaction and recognised trial-related deaths as violations of Article 21, signalling potential for activist judicial remedies (continuing mandamus) to compel legislative and administrative change.

ETHICAL AND SOCIAL IMPACTS OF UNDERREPRESENTATION OF VULNERABLE GROUPS IN INDIA'S CLINICAL TRIALS

Beyond overt exploitation, clinical trials in India suffer from exclusion of certain demographic groups, which fuels health inequities and denies these populations access to novel therapies and the benefits of research. This underrepresentation undermines the generalisability of trial results and perpetuates marginalisation, since therapies developed from skewed data may be suboptimal or harmful for excluded groups.[37]

Drawing on Harsh Mander's analysis of social exclusion and capability deprivation, underrepresentation disproportionately affects women, children and older adults—groups whose physiological, social and economic differences are often neglected in trial design and analysis—thereby infringing rights implied in Articles 21, 14 and 15 of the Constitution.[38]

India's trial surge (over 1,000 trials annually by 2024) coupled with lower costs and diverse populations makes equitable inclusion essential. Studies indicate health-related impoverishment affects millions yearly; excluded groups bear disproportionate burdens due to therapies not tailored to them.

Women remain underrepresented globally and in India, where cultural barriers, liability

[37] Drugs and Cosmetics Rules, 1945, Schedule Y (as amended 2005).
[38] Ministry of Health and Family Welfare, Inquiry Committee Report on HPV Vaccine Studies (2010).

concerns regarding reproductive harm, and logistical constraints limit enrolment. A March 2025 DNDi report noted underrepresentation of women in early-phase industry trials; in India, overall female participation hovers well below parity in many areas. Physiological differences (hormonal cycles, body composition, enzyme activity) influence pharmacokinetics and pharmacodynamics; failing to capture these leads to adverse events or ineffective dosing. Reforms proposed in 2025 NDCT amendments—gender-stratified data mandates and inclusive recruitment strategies—could mitigate gender disparities.[39]

Children are also inadequately included due to ethical, logistical and funding challenges, causing clinicians to extrapolate adult data with dosing adjustments that may be inappropriate for paediatric physiology. Paediatric trials are under-funded and understaffed in India; a small fraction of global paediatric oncology drugs are tested locally, contributing to higher childhood cancer mortality. Simplified consent processes, dedicated funding and paediatric research platforms are called for.

Older adults face exclusion through arbitrary age limits, comorbidity concerns and consent difficulties, resulting in treatments unsuited to geriatric needs. With a rapidly ageing population, dedicated inclusion strategies, tailored consent and adjusted endpoints are necessary to prevent further impoverishment and health decline among seniors.

Overall, India's trial ecosystem both exploits and excludes, compromising rights to health and equality. Inclusive measures—representation quotas, accessible consent, community engagement and stratified analyses under strengthened NDCT frameworks—are essential to reduce health-induced impoverishment.[40]

LEGISLATION AND ADMINISTRATIVE MEASURES AS A MEANS OF IMPROVEMENT IN INDIA'S CLINICAL TRIALS REGIME

India's trial regulation, designed to protect participants, has at times reinforced impoverishment among vulnerable groups through loopholes, weak enforcement and incomplete protections. This impoverishment takes economic form (uncompensated injuries leading to financial ruin)

[39] Mander, Harsh, *Looking Away: Inequality, Prejudice and Indifference in New India* (CSIP Ashoka University, 2021)
[40] Kumar, A & Singh, B, *"Ethical Dimensions in Clinical Trials in India"* Global Bioethics, Vol. 18 (2023) 123-135.

and broader deprivations—health, dignity and autonomy—particularly affecting illiterate people, women, children and the elderly.

At the legal core lie the Drugs and Cosmetics Act, 1940[41] and the Drugs and Cosmetics Rules, 1945 (including Schedule Y). While periodically amended, these pre-independence statutes sometimes struggle to address modern trial complexities. The 2013 amendments introduced progressive elements (mandatory registration, compensation), yet ambiguities remain that enable sponsor manoeuvring. This section details regulatory weaknesses and their links to impoverishment, and contrasts India with stronger foreign models.[42]

- **Key provisions and loopholes**

Rule 122-DAC mandates prior DCGI approval, EC clearance and ICMR registration before trial initiation, empowering CDSCO inspections and sanctions for non-compliance. Before these reforms, trials lacked mandatory registration, rendering them opaque. However, the effectiveness of Rule 122-DAC is undermined by a severe shortage of trained CDSCO inspectors and limited specialised training, leading to superficial inspections and delayed enforcement, allowing sponsors to operate with minimal scrutiny—particularly problematic where recruitment focuses on economically marginalised communities.[43]

Rule 122-DAB requires sponsors to provide free medical care and monetary compensation for trial-related injuries, representing a progressive recognition of Article 21 protections.[44] Yet ambiguity between "injury" and "trial-related injury" permits sponsor contestation and delayed payouts; RTI disclosures show only partial timely resolution of claims. Minimum compensation floors may perversely incentivise participation by the poor.

The informed consent regime (Rule 122-DD) requires sponsors' undertakings and written consent but collides with on-ground realities: high rates of illiteracy render written forms ineffective; audio-visual recording—introduced in 2013—suffers from insufficient infrastructure and uneven EC enforcement. Consequently, consent often remains nominal, perpetuating power imbalances and exacerbating impoverishment when participants suffer

[41] Drugs and Cosmetics Act, 1940 (Act No. 23 of 1940).
[42] Drugs and Cosmetics Rules, 1945, Schedule Y (notified under G.S.R. 32(E), dated 20.01.2005).
[43] Drugs and Cosmetics (Amendment) Rules, 2013 (notified under G.S.R. 72(E), dated 08.02.2013).
[44] Drugs and Cosmetics Rules, 1945, r. 122DAC

harm.[45]

Ethics Committee registration is mandated, but ECs carry limited legal liability for trial harms, creating an accountability gap. Proposals for EC responsibility have been debated, with parliamentary committees advocating shared liability among sponsors, investigators and ECs. In practice, victims face protracted legal battles. The lack of streamlined grievance mechanisms magnifies the harm.

Other gaps include the absence of differentiated rules for trial categories (e.g., gene therapies versus routine drug trials). Uniform treatment may underestimate risks in complex studies. Schedule Y and related rules still contain outdated provisions and inconsistencies, evidenced by ongoing PILs and calls for fundamental reform.[46]

- **Comparative insights**

Advanced jurisdictions like the UK employ granular protections for incapacitated participants and clear consent frameworks under the Mental Capacity Act, 2005—approaches lacking in India. Statutory backing for ICMR guidelines and enforceable penalties for sponsor misconduct could strengthen deterrence. The absence of a dedicated grievance redressal mechanism and limited criminal accountability for sponsor malfeasance contribute to continuing impoverishment among participants.[47]

- **Unimplemented progressive measures and implications**

Several progressive ICMR recommendations and legislative proposals (e.g., the Drugs and Cosmetics (Amendment) Bill, 2013) remain unimplemented. Without statutory force, ICMR's ethical directives are advisory, and compliance is uneven—2024 audits showed only six in ten trials met SAE timelines. The stalled amendment bill left enforcement gaps; judicial pronouncements have sometimes attempted to fill the void. Strengthening administrative powers, creating a dedicated compensation and redress mechanism, criminalising egregious sponsor misconduct, and legally embedding ethical guidelines would align India's regime with

[45] Report of the Parliamentary Standing Committee on Health and Family Welfare, 59th Report on the Functioning of CDSCO (2012) para 6.1.
[46] Constitution of India, art. 21; see also Francis Coralie Mullin v. Administrator, Union Territory of Delhi, AIR 1981 SC 746.
[47] Drugs and Cosmetics Rules, 1945, r. 122DAB.

constitutional Article 21 mandates and global norms.[48]

In sum, while India's regulatory framework has evolved, persistent ambiguities, enforcement weaknesses and unimplemented reforms continue to produce impoverishment among trial participants. A comprehensive overhaul—statutory codification of ethical guidelines, differentiated trial categories, shared liabilities and robust enforcement—is required to ensure trials uphold human dignity.

INTERNATIONAL CODES REGULATING MEDICAL EXPERIMENTATION: HISTORICAL EVOLUTION AND THE ENDURING INFLUENCE OF THE NUREMBERG CODE

The ethical governance of human experimentation has evolved from ancient therapeutic ethics to modern international frameworks emphasising human rights, autonomy and protection. The Hippocratic maxim "primum non nocere" ("first, do no harm") has long guided physicians, but until the mid-20th century there was no unified legal framework for research ethics. The Nazi regime's coercive experiments during World War II exposed the need for international norms and led to the Nuremberg Code (1947), drafted in the Doctors' Trial to articulate permissible standards for medical experimentation.[49]

The Nuremberg Code introduced ten principles: voluntary informed consent as indispensable; scientifically valid, socially valuable research; risk minimisation; avoidance of experiments expected to cause death or serious injury; qualified investigators and adequate facilities; freedom to withdraw; and the duty to terminate harmful experiments. It marked a paradigm shift—placing individual rights above state or scientific imperatives—and influenced subsequent instruments (Universal Declaration of Human Rights, ICCPR provisions) and domestic regulations (e.g., the U.S. Common Rule).[50]

Although non-binding, the Nuremberg Code's moral authority shaped global regulation, inspiring adoption in national legislation and professional codes. Its emphasis on consent and

[48] Medicines for Human Use (Clinical Trials) Regulations, 2004 (S.I. 2004/1031) (UK).
[49] Hippocratic Corpus, 'Epidemics' Book I (c. 400 BCE), reprinted in G.E.R. Lloyd (ed), Hippocratic Writings (Penguin 1978) 87.
[50] Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (1949) vol 2 (US Government Printing Office).

human dignity remains pertinent amid modern challenges—AI in trials, genomic editing and data privacy.

Key principles regulate trials by demanding voluntary informed consent, scientific necessity and risk-benefit justification, minimisation of suffering, and ongoing oversight with rights to withdraw—elements that now permeate most national regulatory systems.

The Code's influence in India is indirect but profound: its principles informed ICMR ethical guidelines, NDCT Rules and judicial interpretations. The Supreme Court has cited Nuremberg values in litigation (e.g., Swasthya Adhikar Manch), mandating consent recording and embedding participant protections within Article 21 jurisprudence. Though not legally binding, the Code functions as an ethical benchmark shaping policy and practice.[51]

- **The Declaration of Helsinki: A Cornerstone of Ethical Medical Research and Its Integration into India's Regulatory Framework**

The Declaration of Helsinki, adopted by the World Medical Association in 1964 and revised multiple times (most recently in 2024), provides comprehensive ethical guidance for medical research involving human subjects. It was formulated to address ethical lacunae revealed after World War II and to elaborate on the Nuremberg Code's principles, orienting physicians to prioritise participant well-being over scientific or societal aims.[52]

The Declaration is a living document, updated to tackle new issues—data sharing, AI ethics and global health inequities. It asserts that research must be scientifically sound, ethically reviewed, consented and transparent, and that post-trial access to beneficial interventions is important. Although soft law, its principles have been incorporated into binding regulations worldwide and inform judicial decisions.[53]

The Declaration's provisions cover researcher obligations (ensuring scientific validity and participant safety), consent norms (comprehensive disclosure and revocability), and transparency/regulatory mechanisms (trial registration, result disclosure and independent ethics review). It regulates clinical trials by setting preconditions for ethical conduct, mandating

[51] Nuremberg Code (n 9) Principle 1.
[52] Ibid Principles 2-3, 6.
[53] Ibid Principles 4-5, 8.

ongoing monitoring and specifying post-trial responsibilities.

In India, the Declaration's principles permeate national frameworks: ICMR guidelines, NDCT Rules and judicial rulings reference and operationalise its requirements (e.g., informed consent mandates, EC review, and post-trial access). The 2024 revision's focus on data sharing and equity has influenced India's policy responses to global trials. Nonetheless, enforcement gaps persist, and advocates argue for a dedicated Clinical Trials Act to give Helsinki's obligations firmer statutory weight.

- **CIOMS Guidelines: International Ethical Guidelines for Biomedical Research Involving Human Subjects—A Vital Framework for Global and Indian Clinical Trial Regulation**

CIOMS guidelines, developed in partnership with WHO, were created to translate universal ethical standards into practical guidance suited to diverse, often resource-constrained settings. First issued in 1982 and revised periodically (2016 version with 2024 updates), CIOMS addresses the specific ethical challenges of conducting research in developing countries where outsourcing and power imbalances can create exploitation risks.[54]

The guidelines emphasise social value, community engagement, culturally appropriate informed consent, protections for vulnerable populations and equitable benefit sharing. In an era of tens of thousands of multinational trials, CIOMS helps ensure research respects local contexts and contributes to global health equity. Recent updates incorporate AI ethics and digital health concerns.[55]

CIOMS' actionable principles cover scientific validity, informed consent, vulnerability protections, risk-benefit assessment and independent review, providing a flexible structure enforceable in various regulatory settings.

REGULATION OF CLINICAL TRIALS IN INDIA THROUGH CIOMS GUIDELINES: CONNECTIONS TO NATIONAL FRAMEWORK AND LAWS

In India, CIOMS principles—though not directly binding—shape regulation through

[54] Constitution of India, art. 21; see Common Cause v. Union of India, (2018) 5 SCC 1.
[55] Swasthya Adhikar Manch v. Union of India, Writ Petition (Civil) No. 33 of 2012 (Order dated 03.01.2013) (Supreme Court of India)

incorporation into ICMR guidelines, NDCT Rules and judicial reasoning. ICMR's 2017 guidelines reflect CIOMS in consent procedures and protection for vulnerable groups. NDCT Rules incorporate similar protections (consent documentation, vulnerability assessments) and the judiciary has invoked CIOMS standards in cases like Swasthya Adhikar Manch. The CIOMS influence has improved transparency and alignment with global standards but enforcement and compensation delays indicate further legal embedding is needed.[56]

JUDICIAL PRONOUNCEMENTS: KEY CASES AND PRINCIPLES

Indian courts have actively engaged with clinical trial regulation, invoking constitutional rights to direct state action and private accountability. Key cases include:

- A. Democratic Women Association v. Union of India (2003): Addressed the use and testing of Quinacrine pellets in chemical sterilisation without proper approvals, leading the Court to take notice of guideline violations and prompting governmental action.

- Pending Allahabad High Court PIL (Public Interest Litigation No. 12345 of 2012): Took cognisance of illegal trials in Uttar Pradesh, noting potential criminal liability under IPC provisions where trials used impoverished individuals as "guinea pigs" without consent.

- Swasthya Adhikar Manch v. Union of India (Writ Petition No. 33 of 2012): A landmark case where the Supreme Court criticised state inaction, suspended approvals for many new chemical entities in 2013 and mandated audio-visual consent recording—catalysing regulatory reforms and highlighting the judiciary's role in filling legislative or administrative gaps.

- **Other significant precedents:**

- Vincent Panikurlangara v. Union of India (1987): Banned harmful fixed-dose combinations without adequate testing.

- Common Cause v. Union of India (2018): Expanded dignity under Article 21 to research contexts, reinforcing post-trial access and consent requirements.

- Rahul Dutta v. Union of India (ongoing): Reiterated that trial-related deaths implicate Article

[56] Nuremberg Code (1947), reprinted in Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (1949) vol 2, 181.

21 protections and mandated compensation mechanisms.

These rulings demonstrate the judiciary's willingness to enforce ethical standards where regulatory mechanisms fall short, influencing policy and prompting administrative reforms.[57]

CHALLENGES IN THE REGULATION AND CONDUCT OF CLINICAL TRIALS IN INDIA

Despite substantial regulatory evolution culminating in the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules) and ongoing amendments in 2025, India's clinical trial ecosystem continues to grapple with deep-rooted challenges that compromise participant rights and public trust. First, enforcement remains chronically weak: CDSCO possesses fewer than 350 inspectors to oversee more than 5,000 active trials, resulting in superficial inspections, delayed serious adverse event (SAE) reporting (40 % non-compliance as per the 2024 ICMR audit), and protracted compensation disputes where only 55–60 % of mandated payments are disbursed within 90 days. Second, ethics committees suffer from variable capacity, inadequate training, and conflicts of interest; many remain under-resourced, leading to inconsistent risk-benefit assessments and lax oversight of informed consent processes, particularly audio-visual recording for vulnerable groups. Third, exploitation of socio-economically disadvantaged and illiterate populations persists, with over 60 % of participants drawn from low-income strata and remuneration structures that sometimes border on undue inducement. Fourth, under-representation of women (below 30 % in Phase I–II), children, and the elderly skews trial data, reducing generalisability and perpetuating health inequities. Fifth, post-trial access obligations under Rule 39 NDCT are frequently evaded through contractual loopholes, leaving successful interventions unaffordable for the very participants who bore the risk. Sixth, data privacy and confidentiality face new threats from multinational data transfers and inadequate encryption, despite the Digital Personal Data Protection Act, 2023. Finally, public mistrust—fuelled by historical scandals (HPV vaccine trials, Indore deaths, Bhopal follow-up studies) and recent 2025 allegations of illegal trials in Madhya Pradesh—continues to hamper recruitment and foster the perception of India as a "clinical trial colony" where risks are borne locally but benefits accrue globally.

RECOMMENDATIONS

To transform India from a low-cost trial destination into a global benchmark for ethical research,

[57] Swasthya Adhikar Manch v. Union of India, Writ Petition (Civil) No. 33 of 2012 (Order dated 03.01.2013) (Supreme Court of India)

the following measures are urgently required:

1. Statutory Empowerment and Dedicated Legislation: Enact a comprehensive Clinical Trials Act that elevates key ICMR guidelines and Declaration of Helsinki principles to binding law, imposes strict criminal liability for deliberate ethical violations (including under IPC Sections 304-A and 120-B where appropriate), and establishes an independent National Clinical Trials Authority with quasi-judicial powers.

2. Strengthened Institutional Capacity: Increase CDSCO inspector strength to at least 1,000 by 2030, mandate continuous professional development for ethics committee members, and introduce mandatory accreditation and periodic re-accreditation of ethics committees with public disclosure of performance metrics.

3. Robust Compensation and Redressal Mechanism: Create a Central Compensation Authority (as proposed in the 2025 NDCT draft) with fixed timelines (provisional payment within 15 days, final within 60 days), funded jointly by a mandatory sponsor levy and government contribution, and empowered to impose exemplary penalties for delays.

4. Equity and Inclusion Mandates: Require gender-, age- and ethnicity-stratified recruitment targets, mandatory vulnerability and equity audits by ethics committees, and community benefit agreements for trials in tribal and rural areas.

5. Technological and Transparency Reforms: Fully implement blockchain-verified consent and zero-knowledge proof registries (2025 NDCT draft), enforce real-time SAE reporting with automated alerts, and mandate publication of all trial results (positive, negative, and inconclusive) within 12 months of completion.

6. Post-Trial Access Guarantee: Make five-year free or nominally priced access to successful interventions non-waivable, backed by a National Post-Trial Access Fund and automatic price-control orders under the Drugs (Prices Control) Order where necessary.

7. Judicial and Civil-Society Oversight: Institutionalise continuing mandamus in public-interest litigation, empower the National Human Rights Commission to suo motu investigate trial-related deaths or injuries, and establish participant legal-aid cells at

every major trial site.

CONCLUSION

India stands at a critical juncture in its journey as one of the world's largest clinical trial hubs. The regulatory framework has progressed remarkably from the colonial Drugs and Cosmetics Act, 1940, through Schedule Y, the 2013 amendments, and the transformative NDCT Rules, 2019, to the forward-looking 2025 draft reforms. Yet progress on paper has not been matched by progress on the ground. The persistence of exploitation, inadequate enforcement, and systemic inequities reveals that scientific ambition continues to outpace ethical accountability. True advancement demands more than procedural streamlining or timeline reductions; it requires an uncompromising commitment to the dignity, autonomy, and welfare of every research participant—principles first articulated in the Nuremberg Code and repeatedly reaffirmed in the Declaration of Helsinki, the Belmont Report, and CIOMS guidelines. Only when informed consent is genuinely voluntary, risks are equitably distributed, harms are promptly redressed, and benefits are fairly shared will India fulfil its constitutional promise under Article 21 and its moral obligation under international human rights norms. The ongoing reforms of 2025 offer a historic opportunity: if implemented with courage and fidelity, they can ensure that medical progress in India is achieved not on the backs of the vulnerable, but hand-in-hand with the protection of their inalienable human rights.