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REGULATORY LOOPHOLES IN POST-TRIAL ACCESS AND INJURY COMPENSATION IN CLINICAL TRIALS: A CRITICAL HEALTH LAW ANALYSIS

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ABSTRACT

The modernisation of biomedical research regulation has prioritised expedited clinical trial approvals, cross-border data harmonisation, and pharmaceutical investment. However, this commercial acceleration has intensified systemic legal vulnerabilities regarding the protection of human research participants. Under contemporary health law regimes, most notably exemplified by India's New Drugs and Clinical Trials Rules, 2019, enacted under the Drugs and Cosmetics Act, 1940, serious normative and statutory ambiguities persist regarding post-trial access to investigational therapies and financial redress for research-related injuries. While international bioethical covenants such as the Declaration of Helsinki and CIOMS International Ethical Guidelines assert that participants who derive clinical benefit should not face abrupt therapeutic abandonment, domestic health laws frequently condition post-trial access upon discretionary approvals, narrow medical criteria, and coercive liability-waiver agreements. Furthermore, statutory compensation frameworks for trial-induced injuries suffer from acute evidentiary asymmetry. Regulatory formulas mechanistically compensate direct physical impairments while routinely excluding indirect adverse events, delayed sequelae, and mental health repercussions, while placing the evidentiary burden of establishing medical causation on vulnerable subjects. This research paper conducts an exhaustive health law critique of the substantive and procedural lacunae governing post-trial continuity and participant compensation. By analysing primary regulatory statutes, statutory amendments, administrative mechanisms of Institutional Ethics Committees, and pivotal judicial jurisprudence, this study exposes how current regulatory frameworks subordinate human rights to pharmaceutical expediency. It concludes by offering concrete, legally enforceable statutory recommendations in a separate section, including the establishment of an independent No-Fault Clinical Trial Compensation Tribunal, statutory prohibition of exculpatory post-trial liability waivers, mandatory pre-licensure expanded access covenants, and the codification of therapeutic continuity as an enforceable statutory entitlement.

Keywords: Clinical Trials Regulation; Health Law Jurisprudence; Post-Trial Access; Therapeutic Continuity; Serious Adverse Events; Clinical Trial Injury Compensation; New Drugs and Clinical Trials Rules 2019; Institutional Ethics Committees; Biomedical Research Governance; Informed Consent.

1. INTRODUCTION

Clinical trials constitute the epistemic foundation of contemporary evidence-based medicine and pharmaceutical innovation. Before any therapeutic molecule, diagnostic biological agent, or medical device achieves public marketing authorization, its pharmacokinetics, efficacy profile, and adverse reaction parameters must be rigorously established through interventional phases involving human participants. Yet, biomedical experimentation occupies an ethically fragile and legally sensitive zone. The clinical trial enterprise operates through an intrinsic structural paradox: individuals are asked to expose their bodily integrity to experimental compounds possessing unknown toxicity and efficacy parameters, primarily to generate scientific data that benefits future patient populations and commercial sponsors.

Historically, the regulatory architecture governing biomedical research developed reactively in response to catastrophic ethical abuses. From the Nuremberg Code of 1947¹ to the Declaration of Helsinki formulated by the World Medical Association,² the core imperative of health law has been the preservation of participant autonomy, safety, and non-exploitation. In developing nations and global clinical trial hubs such as India, the regulatory evolution was propelled into the public consciousness through judicial scrutiny. Landmark public interest litigations, such as the historic proceedings in *Swasthya Adhikar Manch v. Union of India*,³ revealed egregious failures in clinical trial monitoring, widespread lack of genuine informed consent among vulnerable populations, uninvestigated deaths, and the utter absence of financial restitution for experimental injuries. These scandals catalysed sweeping legislative revisions, culminating in the notification of the New Drugs and Clinical Trials Rules, 2019 under the statutory umbrella of the Drugs and Cosmetics Act, 1940.⁴

The New Drugs and Clinical Trials Rules were heralded as a transformative regulatory

¹The Nuremberg Code (1947), reprinted in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No 10*, vol 2 (US Government Printing Office 1949) 181–182.

²World Medical Association, 'WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects' (adopted 1964, as revised 2013).

³*Swasthya Adhikar Manch v Union of India* (2014) 14 SCC 788 (SC); see also the interim orders of the Supreme Court dated 3 January 2013 and 30 September 2013 in Writ Petition (Civil) No 33 of 2012.

⁴New Drugs and Clinical Trials Rules 2019, GSR 227(E) dated 19 March 2019 (Ministry of Health and Family Welfare), made under the Drugs and Cosmetics Act 1940, s 12(1) and s 33(1).

framework designed to introduce predictability, transparency, and ethical oversight.⁵ They codified dedicated provisions governing serious adverse event reporting, instituted statutory formulas for financial compensation, defined timelines for regulatory scrutiny, and incorporated explicit terminology regarding post-trial access. However, a critical legal dissection reveals that the statutory modernisation was heavily slanted toward clinical research facilitation and regulatory streamlining, creating deep structural loopholes in participant protection. While pharmaceutical sponsors enjoy accelerated, time-bound approval mechanisms and generous local trial waiver exemptions, trial subjects continue to confront profound legal uncertainties once the active interventional phase of an experiment terminates. Two prominent areas highlight this regulatory divergence: the enforceability of post-trial access to investigational drugs and the adjudication of compensation for trial-related injuries. When a patient suffering from an oncology disorder, rare genetic ailment, or treatment-resistant chronic condition experiences significant therapeutic benefit from an experimental molecule, the abrupt termination of the trial protocol frequently precipitates severe clinical deterioration or death. Despite international ethical declarations asserting therapeutic continuity rights, health law statutes fail to mandate unencumbered post-trial provision as a binding legal condition.⁶ Instead, domestic regulations create discretionary gateways, encumbered by liability-waiver mandates that force vulnerable patients to surrender fundamental legal remedies against sponsors. Similarly, the legal regime governing clinical trial injury compensation remains procedurally deficient. Although the statutory introduction of an algorithmic formula in the Seventh Schedule of the New Drugs and Clinical Trials Rules attempted to standardize compensatory awards,⁷ the legal framework rests upon an untenable evidentiary presumption. It relies entirely on rigid definitions of causality that mechanistically penalize indirect adverse events, multifactorial clinical deteriorations, and delayed psychological trauma. By leaving the investigative apparatus in the hands of Institutional Ethics Committees and expert review panels that frequently harbor structural conflicts of interest, health law continues to place an insurmountable evidentiary burden upon aggrieved patients. This research paper provides an extensive, doctrinally grounded health law analysis of these loopholes, tracing the statutory evolution, dissecting procedural contradictions, evaluating international benchmarks, and formulating comprehensive legislative reforms.

⁵New Drugs and Clinical Trials Rules 2019 (n4), comprising thirteen chapters, eight Schedules and standardised statutory forms.

⁶New Drugs and Clinical Trials Rules 2019, r 27, read with r 2(1)(cc).

⁷New Drugs and Clinical Trials Rules 2019, Seventh Schedule (rr 39, 40 and 42).

2. STATUTORY FRAMEWORK AND HISTORICAL EVOLUTION OF CLINICAL TRIAL GOVERNANCE

2.1 The Pre-2019 Regulatory Landscape: Drugs and Cosmetics Act, 1940 and Schedule Y

The statutory governance of human clinical trials in India originated within the broad administrative confines of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. For several decades, interventional human studies were governed under Schedule Y of the 1945 Rules,⁸ a regulatory instrument primarily designed to evaluate pharmaceutical quality, manufacturing tolerances, and import standards rather than comprehensive bioethical rights. Schedule Y initially lacked detailed statutory mechanisms for participant protection, serious adverse event causality determination, and mandatory compensation. Clinical trials were treated predominantly as procedural extensions of technical drug approval dossiers.

During the early 2000s, India emerged as an exceptionally attractive global destination for multinational contract research organizations. This growth was driven by vast patient populations, high therapeutic disease burdens, lower operational costs, and a substantial pool of treatment-naïve subjects. However, this commercial expansion far outpaced statutory oversight mechanisms. The existing provisions in Schedule Y provided vague instructions regarding informed consent, lacked robust institutional verification, and contained zero enforceable obligations compelling sponsors to compensate trial victims or provide post-trial therapeutic care. Regulatory authority remained fragmented between state drug controllers and the Central Drugs Standard Control Organization, creating pervasive compliance evasion.

2.2 The Judicial Catalyst: Public Interest Litigation and the Swasthya Adhikar Manch Directives

The systemic failure of the regulatory machinery culminated in intense judicial intervention before the Supreme Court of India. In the landmark litigation *Swasthya Adhikar Manch v. Union of India*,⁹ civil rights organizations and public health advocates presented damning empirical evidence demonstrating widespread exploitation of socially marginalized and illiterate subjects in clinical trials. Severe clinical trials conducted without valid informed consent, undocumented fatalities in vaccine and oncology studies, and the total abandonment of injured participants exposed fundamental fractures in the State's constitutional obligation to

⁸Drugs and Cosmetics Rules 1945, Sch Y (as it stood prior to its substantial replacement by the New Drugs and Clinical Trials Rules 2019).

⁹*Swasthya Adhikar Manch* (n3).

preserve human life and dignity under Article 21 of the Constitution.¹⁰

Taking stern cognizance of these constitutional transgressions, the Supreme Court issued strict directives to the Central Government and the Ministry of Health and Family Welfare. The Apex Court halted the unmonitored approval of clinical trials, demanding the institutionalization of a comprehensive legal framework that guaranteed audio-visual recording of informed consent, strict accreditation of Institutional Ethics Committees, centralized clinical trial registration, and legally binding mechanisms for mandatory medical management and financial compensation. The judicial pressure forced the executive to promulgate interim regulatory amendments, notably GSR 53(E) in 2013,¹¹ which introduced preliminary rules for clinical trial compensation, before undertaking a complete statutory restructuring.

2.3 The Promulgation of the New Drugs and Clinical Trials Rules, 2019

On March 19, 2019, the Ministry of Health and Family Welfare notified the New Drugs and Clinical Trials Rules, 2019, through GSR 227(E),¹² officially superseding Part XA and Schedule Y of the Drugs and Cosmetics Rules, 1945 for new drugs and investigational new drugs. The New Drugs and Clinical Trials Rules established a comprehensive statutory code consisting of thirteen chapters, comprehensive schedules, and standardized statutory forms. The explicit objective was to strike an administrative balance: creating a transparent, predictable, and time-bound approval pathway to stimulate medical innovation while establishing rigorous legal safeguards for human subjects.

Key structural innovations introduced under the new code included the bifurcation of Institutional Ethics Committees into bodies registered for clinical trials and those overseeing biomedical and health research,¹³ strict application processing windows such as 30-day deemed approval for indigenous drugs and 90 days for foreign developments, explicit codified responsibilities for sponsors, and detailed rules governing academic trials. Most importantly for participant rights, Chapter VI codified the statutory procedure for medical management and financial compensation for injury or death, while Rule 27 and Rule 42 formally introduced the legal concept of post-trial access.¹⁴ However, as subsequent legal application has demonstrated, these provisions contain profound structural ambiguities and conceptual loopholes that

¹⁰Constitution of India 1950, art 21; see also *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) 4 SCC 37 (SC), recognising the right to emergency medical treatment as an incident of the right to life.

¹¹Drugs and Cosmetics Rules 1945, Amendment, GSR 53(E) (2013), introducing interim provisions on clinical trial compensation.

¹²New Drugs and Clinical Trials Rules 2019 (n4).

¹³New Drugs and Clinical Trials Rules 2019, Chapter III.

¹⁴*ibid* Chapter VI (rr 39–43), r 27 and r 42.

undermine their protective efficacy.

3. REGULATORY LOOPHOLES IN POST-TRIAL ACCESS (PTA)

3.1 *The Bioethical Mandate: Declaration of Helsinki and CIOMS vs. Domestic Law*

The principle of post-trial access is rooted in the fundamental bioethical tenets of non-exploitation, beneficence, and distributive justice. When individuals accept the physiological risks of testing unproven therapeutic agents, the research enterprise extracts bodily labor to secure proprietary scientific data. Paragraph 34 of the World Medical Association Declaration of Helsinki unequivocally provides that in advance of a clinical trial, sponsors, researchers, and host country governments must make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the study.¹⁵ Similarly, Guideline 6 of the Council for International Organizations of Medical Sciences International Ethical Guidelines for Health-related Research Involving Humans emphasizes that affordable access to successful study interventions must be secured for participants and host communities to prevent exploitation.¹⁶

In stark contrast to these international human rights and bioethical benchmarks, domestic health law in India and many developing jurisdictions treats post-trial access not as an inalienable, enforceable statutory right, but as an optional, discretionary concession. Under Rule 2(1)(cc) of the New Drugs and Clinical Trials Rules, 2019, post-trial access is defined merely as making a new drug or investigational new drug available after completion of a clinical trial in accordance with Rule 27.¹⁷ However, the operative provisions of Rule 27 fail to establish a mandatory affirmative duty upon sponsors to ensure continuous drug supply, transforming what should be a binding legal guarantee into an administrative illusion.¹⁸

3.2 *Rule 27 of the New Drugs and Clinical Trials Rules, 2019: Dissecting Statutory Ambiguities*

A rigorous statutory critique of Rule 27 reveals several fatal legal loopholes that insulate pharmaceutical sponsors from ongoing therapeutic responsibility. First, Rule 27 restricts post-trial access strictly to scenarios where the drug has been demonstrated to be beneficial to a

¹⁵WMA Declaration of Helsinki (n2) para 34.

¹⁶Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans (4th edn, CIOMS 2016) Guideline 6 ('Caring for Participants' Health Needs') and accompanying commentary.

¹⁷New Drugs and Clinical Trials Rules 2019, r 2(1)(cc).

¹⁸ibid r 27.

specific trial subject, the investigator recommends such access, and the Institutional Ethics Committee approves the proposal.¹⁹ By making post-trial access contingent upon the subjective, non-reviewable discretion of the principal investigator and the institutional ethics committee, the law deprives the participant of any autonomous legal cause of action to demand continuation of care.

Second, Rule 27 applies exclusively to cases where the clinical condition for which the trial was conducted has no alternative, satisfactory approved therapy available in the domestic market. This clause creates an immediate statutory trap: if a marginally effective, toxic, or economically unaffordable alternative drug exists on the market, the sponsor is legally relieved of any obligation to supply the superior investigational product. Consequently, patients who achieved clinical stabilisation or remission through novel targeted therapies, monoclonal antibodies, or specialised biological agents find their access abruptly severed, forcing them to revert to ineffective standard-of-care treatments.

3.3 Coercive Exculpatory Clauses: The Mandatory Liability Waiver Dilemma

Perhaps the most legally egregious loophole embedded within Rule 27 is the statutory requirement governing participant consent for post-trial use. The rule explicitly mandates that to receive post-trial access, the trial subject or legal heir must submit a written declaration stating that the sponsor shall bear zero legal liability for any adverse consequences or post-trial usage outcomes.²⁰ In legal terms, the health law statute expressly legitimizes an exculpatory waiver of tortious and regulatory liability as a mandatory prerequisite for receiving continuous life-sustaining medication.

Under general contract law and constitutional jurisprudence, exculpatory contracts signed under severe unequal bargaining power are fundamentally void as contrary to public policy.²¹ In the context of life-saving medical treatment, this requirement is coercive and unconscionable. A terminally ill oncology patient or an individual suffering from a debilitating chronic disease has no real choice when confronted with this waiver: they must either forfeit their legal right to seek compensation for subsequent toxic injuries or face catastrophic therapeutic withdrawal. By codifying this liability shield, Rule 27 subverts the core purpose of health law, sacrificing patient protection to grant corporate immunity.

¹⁹New Drugs and Clinical Trials Rules 2019, r 27(i).

²⁰New Drugs and Clinical Trials Rules 2019, r 27(ii).

²¹Indian Contract Act 1872, s 23, rendering void any agreement the consideration or object of which is opposed to public policy.

3.4 The Therapeutic Vacuum: Sudden Discontinuation and Health Abandonment

When an interventional clinical trial formally concludes, a dangerous temporal interval emerges, commonly termed the therapeutic vacuum. This interval spans the period between protocol completion and final commercial licensure and market launch of the drug. This gap frequently extends over several years due to lengthy dossier evaluations, bureaucratic pricing negotiations, and manufacturing scale-up operations. During this multi-year interregnum, subjects who responded exceptionally well to the trial molecule are left without regulatory channels to maintain treatment unless the sponsor voluntarily establishes an expanded access or compassionate use program.

Medical literature documents that sudden discontinuation of advanced immunotherapies, kinase inhibitors, or psychiatric medications often results in violent rebound phenomena, acute disease progression, physiological crisis, and rapid mortality. Yet, the statutory rules fail to define the duration for which a sponsor must provide post-trial medication. The statute remains silent on whether post-trial supply must persist until the drug becomes commercially accessible in the patient's geographic region, until loss of clinical benefit, or merely for an arbitrary transition window. This legislative silence allows commercial sponsors to terminate drug supplies at will once sufficient clinical data has been harvested, exemplifying profound bioethical abandonment.

3.5 Commercial Realities and Manufacturing Ceilings for Unapproved Molecules

The regulatory breakdown in post-trial access is further exacerbated by legal restrictions governing the manufacture, import, and distribution of unapproved new drugs. Under Chapter X of the New Drugs and Clinical Trials Rules, an investigator or institution seeking to obtain unapproved investigational drugs for compassionate post-trial use must navigate cumbersome procedural hurdles, including submitting Form CT-26 applications to the Central Licensing Authority.²² If a foreign sponsor decides not to commercialize the molecule within the host jurisdiction because the local market lacks sufficient purchasing power, all legal mechanisms for continued access collapse.

Developing nations are frequently utilized as trial testing grounds for specialized orphan therapies or expensive precision oncology drugs that will subsequently be sold exclusively in high-income North American or European markets. Once the trial protocol terminates, the local regulatory infrastructure possesses no statutory leverage to compel a foreign pharmaceutical

²²New Drugs and Clinical Trials Rules 2019, Chapter X and Form CT-26.

company to continue importing the drug free of charge. This exposes an acute form of transnational health injustice, wherein vulnerable local populations assume the biological burdens of experimental safety trials without reaping any durable therapeutic entitlements.

4. SYSTEMIC LOOPHOLES IN CLINICAL TRIAL INJURY COMPENSATION

4.1 Chapter VI and the Seventh Schedule Formula: The Illusion of Mathematical Equity

In an effort to eliminate arbitrary executive discretion and provide predictable liability calculations for sponsors, the New Drugs and Clinical Trials Rules, 2019 codified a standardized mathematical formula within the Seventh Schedule for determining financial compensation in cases of trial-related death or permanent disability.²³ For clinical trial-related death, the formula is codified as:

$$\text{Compensation} = (B \times F \times R) \div 99.37$$

Where:

B represents a baseline quantum historically pegged to minimum statutory wages;

F is a factor based on the age of the deceased derived from the Workmen's Compensation Act, 1923;²⁴ and

R represents a risk factor graded according to the participant's baseline medical status and pre-existing medical risks.

While this mathematical framework appears objective, it embodies deep systemic prejudices and substantive injustices. By tying compensation directly to the age-factor and minimum wage indicators borrowed from industrial labor statutes, the formula places an inherently discriminatory valuation on human life. Older participants, retired individuals, and those with severe baseline morbidities are subjected to drastic mathematical reductions through the risk factor variable R. In practice, a frail, elderly participant suffering from cancer who dies due to lethal algorithmic drug toxicity receives an abysmally low financial award, because the formula presumes their impending mortality diminishes the economic value of their existence.

4.2 The Exclusion of Indirect Adverse Events and Multi-Causal Complications

A critical doctrinal loophole in Rule 42 resides in the stringent statutory definition of what

²³New Drugs and Clinical Trials Rules 2019, Seventh Schedule, cl (a) (formula for compensation in case of clinical trial-related death).

²⁴Workmen's Compensation Act 1923, Sch IV, from which the age-based multiplier 'F' in the Seventh Schedule formula is derived.

constitutes a compensable injury. Under Rule 42(1), financial compensation is legally mandated only when the serious adverse event or death arises directly from one of seven enumerated conditions:²⁵ adverse effects of the investigational product; violation of the approved protocol; failure of expected pharmacological action; administration of a placebo in a placebo-controlled study; adverse effects arising from diagnostic procedures required by the protocol; injury to a child in utero due to parental trial participation; or failure to provide standard care. While this statutory list appears broad, it fundamentally excludes indirect adverse events and complex multi-factorial injuries.

In clinical practice, experimental interventions frequently trigger subtle physiological disruptions that interact unpredictably with an underlying disease, ultimately causing organ failure or secondary systemic collapse. In such multi-causal scenarios, expert committees and sponsor medical monitors routinely categorize the mortality or morbid event as an expected progression of the pre-existing illness, thereby severing the legal causal link to the experimental drug. The law provides no statutory presumption in favor of the trial participant, forcing suffering families into a complex medical causation battle that they are scientifically and financially unequipped to wage.

4.3 Delayed Sequelae, Latent Toxicities, and the Narrow Temporal Horizon

Modern biomedical breakthroughs increasingly involve gene editing, viral vector therapies, stem cell implants, and novel mRNA vaccines. These biological platforms possess complex pharmacodynamic profiles characterized by delayed clinical expression, latent mutagenicity, late-onset autoimmune triggers, and multi-year organ toxicities. Despite these scientific realities, the regulatory framework under the statutory rules imposes a rigidly truncated temporal horizon for adverse event reporting and compensation.

Under Rule 40 and Rule 42, the legal machinery for serious adverse event reporting operates strictly during the active window of the trial or immediate post-trial observation period.²⁶ If an experimental subject develops secondary malignancies, aplastic bone marrow failure, or neurodegenerative deterioration two or three years following trial protocol completion, the statutory framework affords zero legal recourse. The clinical trial file is deemed administratively closed, the ethics committee registration has transitioned, and the sponsor has zero continuing statutory obligation to provide free medical management or monetary compensation. This creates an enormous regulatory loophole through which delayed

²⁵New Drugs and Clinical Trials Rules 2019, r 42(1)(a)–(g).

²⁶New Drugs and Clinical Trials Rules 2019, rr 40, 42.

pharmaceutical toxicities escape all legal accountability.

4.4 Psychological, Cognitive, and Neurological Injuries: The Invisible Harms

The compensation parameters in the Seventh Schedule focus almost exclusively on tangible, observable physical mutilation, anatomical loss, or death.²⁷ The permanent disability percentage schedules borrowed from industrial disability frameworks assess lost limbs, sensory impairment, and gross motor deficits. However, novel neuro-psychiatric molecules, centrally acting compounds, and invasive clinical protocols can induce profound cognitive degradation, chronic psychotic decompensation, crippling depression, and post-traumatic stress disorders. These psychiatric and cognitive injuries are systematically marginalized under the current health law framework. Because subjective psychological distress and psychiatric disability cannot be neatly plotted on the Seventh Schedule's physical impairment charts, victims of drug-induced mental trauma are routinely denied substantive financial restitution. The law fails to recognize that irreversible cognitive impairment destroys human dignity and livelihood just as catastrophically as physical paralysis, exposing an antiquated Cartesian mind-body dichotomy in modern health legislation.

4.5 The Evidentiary Chasm: Causality Assessment Algorithms and Institutional Bias

The procedural mechanism for adjudicating compensation under Rule 42 creates an insurmountable evidentiary barrier for trial subjects. When a serious adverse event occurs, the causality determination progresses sequentially through three bodies: the Principal Investigator, the Institutional Ethics Committee, and the Independent Expert Committee constituted by the Central Licensing Authority.²⁸ At every stage of this administrative chain, structural conflicts of interest and evidentiary opaqueness prevail.

The Principal Investigator and the clinical trial site are financially remunerated by the pharmaceutical sponsor, creating an inherent structural bias against attributing an injury to the investigational drug. Furthermore, Institutional Ethics Committees, despite statutory registration requirements under Chapter III, frequently lack independent pharmacological and legal expertise to challenge sophisticated corporate medical defense dossiers.²⁹ The algorithms utilized for causality assessment, such as the World Health Organization Uppsala Monitoring

²⁷New Drugs and Clinical Trials Rules 2019, Seventh Schedule, cl (b) (permanent disability percentage tables).

²⁸New Drugs and Clinical Trials Rules 2019, r 42(2)–(3).

²⁹New Drugs and Clinical Trials Rules 2019, Chapter III (registration of Ethics Committees).

Centre scale³⁰ or Naranjo Algorithm,³¹ require high thresholds of clinical certainty that are structurally unattainable in Phase I or Phase II exploratory trials where complete biological mechanisms remain scientifically unmapped. Consequently, genuine drug toxicities are routinely classified as unlikely or unclassifiable, automatically terminating the sponsor's statutory compensation liability.

5. COMPARATIVE HEALTH LAW: REGULATORY FRAMEWORKS ACROSS JURISDICTIONS

A comparative assessment of clinical trial jurisprudence reveals differing regulatory philosophies regarding the balance between pharmaceutical market incentives and participant protections. A critical examination of frameworks across the United States, the European Union, and Latin American jurisdictions demonstrates the relative strengths and persistent deficiencies of international health law.

In the Indian jurisdiction, governed by the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019, post-trial access remains discretionary under Rule 27, requiring an absence of market alternatives and an exculpatory liability waiver from the participant. Compensation is determined via a strict statutory formula under the Seventh Schedule, backed by mandatory free medical management, yet it systematically excludes indirect harms. In the European Union, under the Clinical Trials Regulation No 536/2014,³² post-trial access is framed as an ethical requirement aligned with the Declaration of Helsinki, while actual provision is delegated to national member states. However, the European Union enforces a robust mandatory national insurance and indemnification system that covers both physical and cognitive clinical harms.

In the United States, governed by the Federal Food, Drug, and Cosmetic Act alongside 21 CFR Parts 50 and 312,³³ there exists no federal statutory mandate compelling sponsors to provide post-trial access or injury compensation. Instead, participants must rely on voluntary expanded access compassionate use pathways under 21 CFR 312 Subpart I,³⁴ or seek redress through complex common-law tort litigation. In sharp contrast, Brazil's National Health Council

³⁰Uppsala Monitoring Centre, 'The Use of the WHO-UMC System for Standardised Case Causality Assessment' (WHO-UMC) <<https://who-umc.org>> accessed 2024.

³¹Ronald Naranjo and others, 'A Method for Estimating the Probability of Adverse Drug Reactions' (1981) 30 *Clinical Pharmacology & Therapeutics* 239.

³²Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC [2014] OJ L158/1.

³³Federal Food, Drug, and Cosmetic Act 1938, 21 USC § 301 et seq; 21 CFR pts 50, 312.

³⁴21 CFR pt 312, Subpart I (Expanded Access to Investigational Drugs for Treatment Use).

Resolutions, notably Resolution CNS 466/2012,³⁵ establish an absolute, non-negotiable statutory mandate compelling sponsors to provide free, indefinite post-trial access to beneficial therapies, accompanied by strict, comprehensive liability for physical and indirect injuries without allowing any liability waivers.

The United States free-market model treats clinical trial participation primarily as a private contractual assumption of biological risk. Informed consent forms routinely contain standardized exculpatory language informing participants that in the event of injury, no financial compensation or free medical care will be provided beyond immediate emergency stabilization. Injured American subjects must navigate tort actions alleging medical negligence or strict products liability, but these actions face formidable common-law barriers including the learned intermediary doctrine³⁶ and federal pre-emption hurdles established in landmark decisions like *Wyeth v. Levine*³⁷ and *Riegel v. Medtronic*.³⁸

In the European Union, Regulation No 536/2014 establishes a cohesive administrative framework through the Clinical Trials Information System. The regulation mandates that every trial application include verified proof of an insurance or indemnification mechanism covering any damage suffered by a participant.³⁹ Furthermore, European compassionate use programs established under Article 83 of Regulation No 726/2004⁴⁰ provide structured, state-monitored early access frameworks that prevent the immediate therapeutic abandonment commonly witnessed in developing markets.

Brazil represents the most progressive, participant-protective health law framework in the global South. Under Resolution CNS 466/2012, sponsors conducting clinical research in Brazil are legally mandated to guarantee all trial subjects free, continuous, and indefinite access to the investigational drug for as long as it demonstrates clinical benefit, even after the trial concludes and regardless of commercial registration status.⁴¹ Brazilian federal courts have repeatedly affirmed that under Article 196 of the Federal Constitution,⁴² the right to health renders any

³⁵Conselho Nacional de Saúde (Brazil), Resolução No 466, de 12 de dezembro de 2012 (Brazilian National Health Council Resolution 466/2012); the precise scope of its post-trial access and non-waiver provisions, as characterised in this paper, merits independent verification against the current consolidated text and subsequent CONEP guidance.

³⁶See generally Restatement (Third) of Torts: Products Liability § 6(d) (American Law Institute 1998), addressing the adequacy of warnings for prescription drugs and the learned intermediary rule.

³⁷*Wyeth v. Levine*, 555 US 555 (2009).

³⁸*Riegel v. Medtronic Inc.*, 552 US 312 (2008).

³⁹Regulation (EU) No 536/2014 (n31) art 76.

⁴⁰Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency [2004] OJ L136/1, art 83.

⁴¹Resolução CNS 466/2012 (n33).

⁴²Constitution of the Federative Republic of Brazil 1988, art 196.

corporate cessation of life-saving trial medication an unconstitutional violation of human dignity, demonstrating that high research activity can coexist with robust human rights protections.

6. RECENT AMENDMENTS AND CONTEMPORARY REGULATORY SHIFTS

6.1 Contract Research Organization Registration and Direct Accountability Mandates

In the years following the initial rollout of the New Drugs and Clinical Trials Rules, 2019, operational realities exposed significant enforcement deficits, particularly regarding the pivotal role of Contract Research Organizations. Because foreign pharmaceutical sponsors cannot directly hold regulatory permissions in India without a domestic corporate presence, they routinely delegate full operational, monitoring, and adverse event reporting responsibilities to Indian contract entities. However, the original 2019 rules failed to formally register or impose direct statutory liability upon these organizations, allowing multinational sponsors and local contractors to engage in mutual liability shifting.

To address this regulatory loophole, comprehensive statutory amendments were notified by the Ministry of Health and Family Welfare,⁴³ enforcing mandatory statutory registration, accreditation, and direct accountability for all Contract Research Organizations operating within the jurisdiction. Under these reforms, contract research bodies are legally classified as co-responsible entities under the Drugs and Cosmetics Act. If a serious adverse event occurs or compensation is defaulted, regulatory authorities can now initiate immediate administrative suspensions, debarments, and financial penalties directly against the local contract research entity, curtailing corporate evasion.

6.2 Accelerated Approval Pathways and the Marginalization of Safety Vigilance

Simultaneously, recent administrative amendments have intensified the drive toward accelerated drug approvals. Under Rule 101 of the New Drugs and Clinical Trials Rules, the Central Licensing Authority has expanded its discretionary authority to grant complete waivers of local clinical trials for drugs already approved in designated reference markets, such as the United States, European Union, United Kingdom, Japan, Australia, and Canada.⁴⁴ While this mechanism accelerates access to life-saving oncology and rare disease medications, it

⁴³New Drugs and Clinical Trials Rules 2019, as amended by subsequent notifications of the Ministry of Health and Family Welfare introducing mandatory registration of Contract Research Organizations.

⁴⁴New Drugs and Clinical Trials Rules 2019, r 101.

introduces dangerous pharmacogenomic blind spots.

By waiving local clinical evaluation in diverse domestic populations possessing distinct genetic polymorphisms, nutritional profiles, and metabolic phenotypes, the regulatory regime heightens the probability of unexpected adverse events occurring during Phase IV post-marketing surveillance. Compounding this risk, the statutory mechanisms for reporting and compensating injuries occurring during Phase IV observational or academic trials remain far more relaxed than those governing Phase II and III trials, exposing the public to unmonitored pharmaceutical hazards.

6.3 The Digitization of Informed Consent: Audio-Visual Mandates vs. Ground Realities

One of the major statutory triumphs arising from the Swasthya Adhikar Manch litigation was the mandatory requirement for audio-visual recording of informed consent for vulnerable participants in trials involving new chemical entities. The statutory rules institutionalized this safeguard under the Third Schedule.⁴⁵ However, contemporary field assessments reveal that the audio-visual recording process has degenerated into a hollow, ritualistic compliance exercise.

Investigators frequently treat the camera as a defensive evidentiary tool to establish formal legal compliance rather than genuine intellectual comprehension. Institutional Ethics Committees rarely conduct forensic audits of recorded consent interactions to verify whether the trial subject understood complex genetic risks, the non-therapeutic nature of exploratory research, or the severe limitations governing post-trial drug availability. When linguistic barriers, socioeconomic disparities, and clinical therapeutic misconceptions converge, the digital recording serves to insulate the sponsor against subsequent failure-to-warn malpractice claims, weaponizing the protective mechanism against the participant.

7. CRITICAL ANALYSIS: THE COMMODIFICATION OF VULNERABILITY IN BIOMEDICAL RESEARCH

7.1 Structural Inequity and the Health-Poverty Nexus

The governance of clinical trials cannot be analysed in isolation from the prevailing political economy of healthcare delivery. In developing societies characterised by massive out-of-pocket medical expenditures, systemic underfunding of public healthcare, and millions of

⁴⁵New Drugs and Clinical Trials Rules 2019, Third Schedule (conduct of clinical trial, including audio-visual recording of informed consent for vulnerable subjects).

underinsured citizens, clinical trial participation is rarely an unconstrained, autonomous decision. For an impoverished patient diagnosed with advanced-stage carcinoma, an experimental clinical trial represents the sole available avenue to receive modern diagnostic imaging, specialised oncology consultations, and cutting-edge biopharmaceutical molecules. This structural deprivation creates a pervasive condition of therapeutic misconception,⁴⁶ wherein desperate patients genuinely perceive the research experiment as personalised medical therapy administered for their personal cure. Pharmaceutical sponsors and recruiting investigators capitalise on this health-poverty nexus, enrolling socioeconomically disadvantaged subjects who are least capable of evaluating technical consent disclosures or demanding post-trial therapeutic continuity. When the trial protocol ends and the free ancillary medical care evaporates, these patients are thrust back into an underfunded public hospital ecosystem incapable of managing their complex, drug-dependent clinical states.

7.2 The Failure of the Institutional Ethics Committee as a Fiduciary Shield

In bioethical and health law doctrine, the Institutional Ethics Committee is conceptualized as an independent fiduciary guardian entrusted with defending participant welfare against institutional and commercial avarice. Under Chapter III of the New Drugs and Clinical Trials Rules,⁴⁷ every trial protocol, informed consent document, post-trial access scheme, and adverse event report must receive committee review. However, the operational reality of ethics committees across private and academic institutions reveals severe institutional capture.

The overwhelming majority of institutional ethics committees depend upon the host hospital or research institute for administrative infrastructure, honoraria, and operational resources. Furthermore, institutional leaders routinely pressure committee members to issue rapid protocol clearances to capture lucrative sponsor funding contracts. Independent members, laypersons, and legal experts on these committees are frequently sidelined during technical deliberations, reducing the ethics review process to a superficial administrative rubber-stamping mechanism. By failing to rigorously interrogate post-trial access covenants and blindly endorsing sponsor-drafted causality denials, ethics committees have largely abdicated their legal role as fiduciary protectors of human subjects.

⁴⁶On the concept of therapeutic misconception generally, see Paul S Appelbaum, Loren H Roth and Charles W Lidz, 'The Therapeutic Misconception: Informed Consent in Psychiatric Research' (1982) 5 International Journal of Law and Psychiatry 319.

⁴⁷New Drugs and Clinical Trials Rules 2019, Chapter III.

8. SUGGESTIONS AND REFORM FRAMEWORK

To remediate the severe normative and statutory deficits identified in contemporary health law, comprehensive legislative, institutional, and procedural reforms must be enacted. The following dedicated recommendations provide an actionable roadmap for restructuring clinical trial governance to align pharmaceutical innovation with human rights and therapeutic justice, presented in detailed narrative form across core legal dimensions.

Regarding statutory codification of therapeutic continuity, the Central Government must amend Rule 27 of the New Drugs and Clinical Trials Rules, 2019⁴⁸ to transform post-trial access from a discretionary privilege into a mandatory, legally enforceable statutory obligation. The amended rule must establish that whenever a trial participant derives verified clinical benefit from an investigational product during an interventional study, the sponsor and its contractual representatives are legally bound to supply the product free of cost without interruption. This statutory duty must persist until the therapeutic agent is granted domestic market approval and becomes practically accessible through public health insurance, or until an independent medical board determines that the participant has ceased to derive clinical benefit.

Regarding the statutory invalidation of exculpatory liability waivers, the statutory requirement embedded within Rule 27 that forces participants to declare that the sponsor shall bear zero liability for post-trial use must be immediately repealed. The statute should expressly declare all exculpatory liability waivers, indemnity covenants, and rights forfeitures signed by clinical trial participants void ab initio as contrary to public policy and constitutional protections under Article 21.⁴⁹ Health law must affirm that ongoing post-trial administration of experimental drugs retains standard statutory pharmacovigilance and product safety liabilities that cannot be extinguished by private contracts.

Regarding pre-licensure expanded access protocols, the Central Licensing Authority must mandate that no clinical trial application shall be approved unless the sponsor submits a detailed Pre-Licensure Expanded Access protocol alongside the Phase III study design. This protocol must specify clear administrative mechanisms, manufacturing allocation quotas, and logistical pathways for seamlessly bridging participants from trial closeout to commercial availability. The inclusion of an audited post-trial transition plan must become a mandatory statutory criterion for granting trial clearance, ensuring that supply continuity is legally settled before the first human subject is enrolled.

⁴⁸New Drugs and Clinical Trials Rules 2019, r 27, as discussed in Section 3.2 above.

⁴⁹Constitution of India 1950, art 21; Indian Contract Act 1872, s 23.

Regarding independent adjudication of injuries, the current procedural model under Rule 42,⁵⁰ which places causality determination in the hands of conflicted institutional ethics committees and closed expert panels, must be replaced with a permanent, statutory National Clinical Trial Compensation Tribunal. Operating as an independent judicial body headed by a retired High Court judge and supported by independent pharmacologists, bioethicists, and patient advocates, this tribunal would exercise exclusive jurisdiction over serious adverse event compensation disputes. The tribunal must operate on an administrative no-fault compensation doctrine,⁵¹ presuming legal causation whenever a statistically recognized adverse event arises during or within twelve months following an interventional trial, unless the sponsor proves an independent intervening cause by clear and convincing evidence.

Regarding participant social security, Parliament should legislate a dedicated National Clinical Trial Social Security Fund to guarantee that victims of clinical trial injuries and their surviving legal heirs receive prompt financial restitution without enduring prolonged bureaucratic or corporate litigation. Sponsored by a mandatory, non-refundable regulatory levy imposed upon every commercial clinical trial application submitted in the country, this independent fund would provide immediate interim financial support and medical coverage upon the occurrence of a serious adverse event. If a foreign sponsor defaults or enters corporate bankruptcy, the fund guarantees that injured subjects are not left destitute.

Regarding statutory compensation formula restructuring, the mathematical formula in the Seventh Schedule⁵² must be radically overhauled. The baseline factor B must be decoupled from antiquated minimum wage laws and tied to national living wage benchmarks or per-capita healthcare expenditure metrics. Furthermore, the discriminatory risk factor variable R, which reduces awards for elderly or chronically ill individuals, must be eliminated entirely. The statutory compensation schedule must explicitly recognize and compensate psychiatric degradation, severe depressive states, loss of cognitive capacity, and indirect adverse events resulting from multi-system organ strain, providing comprehensive restitution for non-anatomical injuries.

Regarding institutional insulation, health law must mandate the financial and administrative decoupling of Institutional Ethics Committees from clinical trial sites and sponsor funding.⁵³ Ethics review fees should be pooled into an independent, state-managed escrow fund and

⁵⁰New Drugs and Clinical Trials Rules 2019, r 42.

⁵¹See, by analogy, the no-fault accident compensation model under the Accident Compensation Act 2001 (New Zealand), which dispenses with proof of fault as a precondition for statutory compensation.

⁵²New Drugs and Clinical Trials Rules 2019, Seventh Schedule, as discussed in Section 4.1 above.

⁵³New Drugs and Clinical Trials Rules 2019, Chapter III, as discussed in Section 7.2 above.

distributed to committees via centralized administrative mechanisms. Furthermore, ethics committee members must receive mandatory, accredited bioethics and legal training, and all adverse event causality deliberations must be transcribed, archived, and accessible to aggrieved participants under open-access public health disclosure norms.

9. CONCLUSION

The legal governance of biomedical clinical trials occupies a defining frontier of modern health law, where the imperatives of biopharmaceutical innovation, corporate profitability, and fundamental human rights collide. The modernisation of drug regulation, most prominently embodied in the New Drugs and Clinical Trials Rules, 2019, successfully introduced operational predictability and procedural standardisation for pharmaceutical developers. However, by prioritising accelerated approvals, deemed clearances, and local clinical trial waivers, the regulatory machinery has left alarming gaps in the core protections owed to human research participants.

As this critical analysis has demonstrated, the current legal regime governing post-trial access and injury compensation suffers from profound statutory contradictions. Rule 27 transforms what should be an inalienable bioethical entitlement into an uncertain, discretionary privilege, while coercing vulnerable patients into executing unconscionable liability waivers that abandon their basic legal remedies. Concurrently, the compensation architecture codified under Chapter VI and the Seventh Schedule⁵⁴ operates through an inflexible mathematical formalism that discriminates against elderly and chronically ill subjects, marginalizes indirect and delayed biological injuries, and forces victims into an insurmountable causality battle against structurally conflicted institutions.

A truly robust health law regime cannot permit the bodily integrity and therapeutic security of clinical trial subjects to be treated as expendable externalities in the pursuit of pharmaceutical commercialization. The participants who shoulder the physiological hazards of experimental medicine are not passive statistical data points; they are human rights bearers entitled to substantive fiduciary care, continuous therapeutic access, and swift, unencumbered redress for trial-induced harm. Only through decisive legislative amendments, the establishment of an independent no-fault compensation tribunal, the abolition of exculpatory waivers, and the statutory codification of therapeutic continuity rights can health law fulfill its constitutional and ethical mandate to protect human life, dignity, and justice in biomedical research.

⁵⁴New Drugs and Clinical Trials Rules 2019, Chapter VI and Seventh Schedule.