CONSENT, CARE AND CONSEQUENCE: CLINICAL TRIALS, ETHICAL OVERSIGHT AND ACCOUNTABILITY IN MEDICAL RESEARCH

Shakthi Samiya S, The Tamil Nadu Dr. Ambedkar Law University

ABSTRACT

Every medicine in a pharmacy was once an experiment on human beings. Clinical trials are how medicine advances, and they are also the setting in which the gap between science and ethics is widest. Participants accept risk, usually without personal benefit guaranteed, for the sake of knowledge that will serve others. This article examines how Indian law regulates that bargain. It begins with the ethical instruments that shaped the field (the Nuremberg Code, the Declaration of Helsinki, the Belmont Report) and the Indian framework built on them: Articles 14 and 21 of the Constitution, the Drugs and Cosmetics Act, 1940, the New Drugs and Clinical Trials Rules, 2019, and the ICMR National Ethical Guidelines, 2017. It explains the architecture of oversight, the anatomy of valid informed consent, the no-fault compensation scheme, and the distribution of liability among sponsors, contract research organisations, investigators, institutions and ethics committees. It also covers the civil, criminal, regulatory and constitutional consequences of misconduct. The study traces the Indian crisis of 2010–2013 and the Supreme Court's intervention in *Swasthya Adhikar Manch*, and argues that India now has a strong rulebook but still faces a verification problem: ensuring that consent is real, ethics committees are independent and compensation actually reaches those harmed. It ends with reforms for each.

Keywords: Clinical trials; Informed consent; Ethics committee; New Drugs and Clinical Trials Rules 2019; Declaration of Helsinki; Compensation for trial injury; Vulnerable participants; Medical ethics; Sponsor liability; Accountability.

1. Introduction

A patient who is treated gets care shaped by the patient's needs. A participant in a trial is treated according to a *protocol* shaped by the needs of the study. Sometimes she receives the **experimental drug**, sometimes the **standard drug** and sometimes a **placebo**, and often neither she nor her doctor knows which. Medicine's usual promise, that everything done is for the patient's good, is deliberately set aside for the sake of generating reliable evidence.

That is why clinical research needs its own ethics and its own law. Ordinary medical negligence asks whether a doctor fell short of accepted practice. A trial asks harder questions:

- Was the participant genuinely free to say no?
- Did she understand that this was research, not treatment?
- Who checked, independently, that the risks were justified?
- If she is harmed by a drug no one yet understands, who pays?

The modern law of research ethics was written in response to failures. The **Nazi medical experiments** led to the **Nuremberg Code (1947).** The **thalidomide tragedy** of the early 1960s exposed what untested drugs can do. The **Tuskegee syphilis study**, in which treatment was withheld from Black men for decades, produced the **Belmont Report (1979).** India's own moment came between 2010 and 2013, when reports of deaths and serious adverse events, uncompensated injuries, unscrupulous consent practices and ethics committees that rubber-stamped protocols reached the Supreme Court. Reform followed, culminating in the **New Drugs and Clinical Trials Rules, 2019.**

This article takes a participant's-eye view. Part 2 defines the field and maps the law. Part 3 follows a single participant through a trial to explain the concepts. Part 4 collects the landmark decisions. Part 5 analyses the gaps between rules and reality, Part 6 offers suggestions and Part 7 concludes.

2. Definitions and Legal Framework

2.1 Key definitions

Clinical trial. A systematic study of a new drug in human subjects to generate data on

its clinical, pharmacological (pharmacokinetic and pharmacodynamic) and adverse effects, with the objective of establishing its safety, efficacy or tolerance **(New Drugs and Clinical Trials Rules, 2019, Rule 2).**

New drug. A drug not previously approved in the country, or one for which a new claim, such as a new indication, dosage form or route, is proposed. The Rules define the term widely so that an approved molecule used in a new way is also treated as a new drug.

Phases of a trial. A trial moves through stages that expand in scale as evidence accumulates:

Phase	**Participants**	**Question**
Phase I	Small group, often healthy volunteers	Is it safe? What dose is tolerated?
Phase II	A few hundred patients	Does it seem to work? What side effects appear?
Phase III	Hundreds to thousands of patients	Is it better than existing treatment?
Phase IV	Post-marketing	What happens in the real world over time?

Sponsor. The person or organisation (usually a pharmaceutical company) that takes responsibility for initiating, managing and financing the trial.

Investigator. The doctor responsible for conducting the trial at a particular site.

Contract Research Organisation (CRO). A body to which the sponsor delegates trial functions.

Ethics Committee (EC). An independent body of medical and non-medical members that reviews protocols and protects the rights, safety and wellbeing of participants. It is called an **Institutional Review Board (IRB)** in some systems.

Informed consent. A voluntary agreement given after the participant has been told, in

a language she understands, about the purpose, procedures, risks, benefits, alternatives, confidentiality and her right to withdraw at any time without penalty.

Serious Adverse Event (SAE). Any untoward medical event during a trial that results in death, hospitalisation, disability, a birth defect or a life-threatening situation.

Vulnerable participants. Persons whose capacity to give free consent is compromised or who are at risk of being exploited: children, pregnant women, persons with mental illness, prisoners, the illiterate, the economically and socially disadvantaged and those in dependent relationships (such as students of an investigator).

2.2 The ethical foundations

Instrument	Core contribution
Nuremberg Code (1947)	"Voluntary consent of the human subject is absolutely essential."
Declaration of Helsinki (World Medical Association, 1964, revised several times, most recently in 2024)	The primary statement of physician-researcher ethics. It states that the participant's wellbeing takes precedence over the interests of science and requires independent ethical review.
Belmont Report (1979)	Three principles: *respect for persons*, *beneficence* and *justice*.
CIOMS International Ethical Guidelines (2016)	Practical guidance on applying these principles, particularly in resource-limited settings.
ICH Good Clinical Practice (GCP)	The international quality standard for trial design, conduct and reporting.
ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)	India's own code, built on the principles of essentiality, voluntariness, non-exploitation, social responsibility, privacy, risk minimisation, professional competence and accountability.

These are **not binding statutes**. In India they operate as the interpretive backdrop to the Rules, and courts treat them as **persuasive standards**.

2.3 The constitutional foundation

- **Article 21.** The right to life and personal liberty includes bodily integrity, dignity and health. An unconsented or exploitative experiment on a person's body engages Article 21 directly.

- **Article 14.** Targeting the poor, the illiterate or marginalised groups as convenient participants raises a question of arbitrariness and unequal protection.

- **Articles 32 and 226.** Writ remedies for systemic failure, which is how the *Swasthya Adhikar Manch* litigation reached the Supreme Court.[1]

- **Article 51A(h)** and the Directive Principles **(Articles 38, 39(e), 47)** support the pursuit of scientific temper and public health. The pursuit of science is valued, but it cannot be bought with the exploitation of the poor.

2.4 The statutory map

Source	Relevance
Drugs and Cosmetics Act, 1940	The *parent statute*. The Central Government is **empowered to make rules** under **Ss. 12 and 33**. Contravention of its provisions attracts **penalties** under **Chapter IV (including S. 27).**
New Drugs and Clinical Trials Rules, 2019 (NDCT Rules)	The *principal regulatory code*. It covers permissions for trials, the registration and duties of ethics committees, informed consent, safety reporting, compensation for injury or death, obligations of sponsors and investigators, and inspection. It **replaced Schedule Y of the Drugs and Cosmetics Rules, 1945** and the **2013 amendments (Rules 122DAA–122DAE).**
Medical Devices Rules, 2017	Governs clinical investigation of medical devices.
ICMR Guidelines, 2017 and **CDSCO Good Clinical Practice Guidelines**	Ethical and operational standards; the NDCT Rules require adherence to GCP.
Clinical Trials	A public registry. Prospective registration of trials has been required

[1] (2013) 4 SCC 1, (2013) 13 SCALE 146

Source	Relevance
Registry – India (CTRI)	in India since 2009.
National Medical Commission Act, 2019	Disciplinary consequences for doctors who violate research ethics.
Bharatiya Nyaya Sanhita, 2023	**S. 106 (death by negligence), S. 125 (acts endangering life or personal safety), Ss. 26, 27 and 30 (good-faith acts and consent)** and **S. 318 (cheating),** where participants are deceived.
Mental Healthcare Act, 2017	Restricts research involving persons with mental illness and requires safeguards.
Digital Personal Data Protection Act, 2023	Data protection obligations, relevant to participants' medical data.
Indian Contract Act, 1872 and **common law of tort**	Civil remedies for breach of duty and negligence.

2.5 The architecture of approval

Under the **NDCT Rules**, a sponsor must obtain permission from the **Central Licensing Authority** (the Drugs Controller General of India, DCGI, through CDSCO) before conducting a trial, and also approval from the **registered Ethics Committee** of each trial site. Timelines are set by the Rules (**30 working days** for drugs discovered in India, **90 working days** otherwise). The investigator must be qualified and the site must be suitable. The trial must be registered on CTRI. Safety reports must flow in time-bound steps: the investigator reports an SAE within **24 hours**, the sponsor reports to the regulator within **14 days,** and the EC gives its opinion on the cause and compensation, also within a fixed period.

3. The Concept in Detail

3.1 A running illustration: Lakshmi's trial

Lakshmi, 52 years old, is a daily-wage worker with Type 2 diabetes. A hospital coordinator approaches her at an outpatient clinic and says there is "a new, free medicine that is better than what you take now". We will follow her through six stages. At each stage, the law asks a different question.

Stage 1: The invitation (voluntariness). The coordinator is also her treating doctor's assistant. Lakshmi fears that refusing might affect her care. This is the problem of *undue influence*. Consent given because refusal seems risky is not free consent.

Stage 2: The consent (understanding). She is handed a 14-page form in English and told to sign. She is not literate, so she gives a thumbprint. Nobody tells her that she might receive a placebo, that she may withdraw, or that the drug may have serious side effects.

Stage 3: The protocol (independent review). The Ethics Committee approved this study in a ten-minute meeting, without examining the risk-benefit balance or the plan for compensation.

Stage 4: The experiment (risk and equipoise). Lakshmi is randomised to the experimental arm. After eight weeks she develops kidney complications.

Stage 5: The aftermath (reporting and compensation). The investigator delays reporting the event. The sponsor claims that her illness is unrelated. The CRO says the hospital is responsible, and the hospital says the investigator is.

Stage 6: The data (privacy). Her records, with her name and village, appear in a presentation shared across a research network.

Each stage matches a legal and ethical principle explained below.

3.2 Pillar one: independent ethical review

The **Ethics Committee** is the participant's institutional advocate. Under the NDCT Rules, an EC must be **registered** with the licensing authority and must have a **minimum of seven members**. These include a chairperson from outside the institution, a member-secretary, a medical scientist, a clinician, a legal expert, a social scientist or representative of a non-governmental voluntary agency, and a lay person. The EC reviews the protocol, the investigator's qualifications, the consent documents, the plan for managing adverse events and the provision for compensation. It monitors the trial after approval and can suspend or withdraw it.

The ethical logic is that **the person who stands to gain from the trial cannot be the only person judging whether it is acceptable.** An EC that is dominated by the host

institution's own staff or approves protocols without deliberation defeats this purpose. In Lakshmi's case, Stage 3 is where the system has already failed.

Equipoise is the principle that makes a trial ethically defensible. There must be genuine uncertainty in the expert community about which treatment is better. If it is already known that Treatment A is superior, assigning Lakshmi to Treatment B knowingly disadvantages her.

Placebo use is allowed only where no proven treatment exists, or where withholding the standard treatment would cause no serious or irreversible harm. A diabetic who is given a placebo instead of her existing medication is at risk of a real and avoidable harm.

3.3 Pillar two: informed consent

Consent is not a signature. It is a *process*. The law and the ICMR Guidelines require the following elements:

Element	**Meaning**	**Lakshmi's failure**
Disclosure	Purpose, procedures, risks, benefits, alternatives, compensation and right to withdraw	Not disclosed
Comprehension	Information in a language and manner the participant understands	English form, no explanation
Voluntariness	No coercion, inducement or fear of losing care	Fear of losing treatment
Documentation	Written consent, with an independent witness for illiterate participants	Thumbprint without a witness or explanation
Audio-visual recording	Required in India for the consent process, with the recording preserved	Absent
Ongoing consent	New risk information must be shared and the participant may withdraw at any time	Not honoured

Indian regulators introduced **mandatory audio-visual recording** of the consent process after the **2013 Supreme Court directions**, because paper consent had proved easy to forge or manufacture. For vulnerable participants, consent must be obtained with greater safeguards, including a **legally acceptable representative** where the participant lacks capacity,

with the participant's own assent obtained wherever possible.

The most important conceptual risk here is the **therapeutic misconception**: the belief of participants that the trial is designed for their personal benefit. A participant who thinks "the doctor is giving me the best treatment" has not understood that her treatment is determined by a protocol and a randomiser. As seen in *Samira Kohli*, consent to one act is not consent to another. Consent to *treatment* is not consent to *experimentation*.[2]

3.4 Pillar three: risk, benefit and justice

The ethical principle of **beneficence** requires that risks to participants be minimised and be reasonable in relation to the anticipated benefits and the importance of the knowledge gained. **Justice** requires that the burdens and benefits of research be shared fairly. This has direct consequences:

- A trial should not be conducted on the poor merely because they are cheaper and easier to recruit, if the resulting drug will be unaffordable to them.
- **Post-trial access** is the idea that participants should continue to receive a beneficial treatment after the trial ends. The Declaration of Helsinki and the ICMR Guidelines both require sponsors to plan for this.
- **Payments** to participants may compensate for time and inconvenience, but not be so large as to lure the poor into taking risks they would otherwise refuse (*undue inducement*).

3.5 Pillar four: safety reporting and monitoring

Trials are monitored by **Data Safety Monitoring Boards** (independent experts who review accumulating data and can stop a study early) and by regulatory inspection. When harm occurs, the **reporting chain** is meant to operate like an alarm: investigator (24 hours), sponsor to regulator (14 days) and the EC's analysis. A delay in this chain, as in Lakshmi's Stage 5, is

[2] AIR 2008 SUPREME COURT 1385, 2008 AIR SCW 855, 2008 (2) ALL LJ 711, 2008 (2) AIR BOM R 354, (2008) 2 MAD LW 336, (2008) 1 RAJ LW 853, 2008 (2) SCC 1, (2008) 1 RECCIVR 525, (2008) 1 SCALE 442, (2008) 39 OCR 593, (2008) 2 PUN LR 213, (2008) 1 ICC 705, (2008) 1 CTC 392 (SC), (2008) 2 ACJ 747, (2008) 2 MAD LJ 662, (2008) 1 RECCRIR 670, (2008) 1 CPJ 56, 2008 (2) ALLMR (NOC) 41, (2008) 5 BOM CR 373

itself a violation.

3.6 Pillar five: compensation, a no-fault promise

Indian law makes a distinctive choice. In ordinary medical negligence, a patient must prove breach of duty. In a trial, the law recognises that the participant has accepted a risk *on behalf of society*, and that proving fault in a novel experiment is practically impossible. The NDCT Rules therefore provide:

1. **Free medical management** for any injury occurring during the trial, for as long as required, whether or not the injury is related to the trial.

2. **Financial compensation** where the injury or death is *related to* the trial, paid by the sponsor, regardless of negligence. It is determined by a formula set out in the Rules, on the recommendation of the Ethics Committee and a regulatory expert committee, with the licensing authority deciding within a fixed period.

3. Compensation is payable to the participant or, in case of death, to the nominee or legal heirs.

4. The Rules identify circumstances in which an injury is treated as *related to the trial* (for example adverse effects of the investigational product, a procedure required by the protocol, or a placebo-related injury) and those in which it is not (for example the natural progression of the disease, or violation of the protocol by the participant).

This mechanism is a policy statement: *the cost of research injury belongs to those who profit from the research.* It is a distinct route from tort, though a participant is not barred from also suing for negligence where it exists.

3.7 Who is liable? The responsibility map

Party	**Primary role**	**Responsibility**
Sponsor	Initiates and funds	Ultimately answerable for compensation, for trial quality and for data integrity. Under the framework, delegation to a CRO does not relieve it of its responsibilities.
CRO	Operates	Answerable for the functions it has taken on; contractual

Party	Primary role	Responsibility
	delegated functions	and tortious liability.
Investigator	Conducts the trial at the site	Consent, protocol compliance, safety reporting, participant welfare. Faces disciplinary, civil and criminal exposure.
Institution / Hospital	Hosts the site	Vicariously liable for its employees' wrongs; directly liable for inadequate facilities or oversight.
Ethics Committee	Independent reviewer	Accountable for approval and monitoring failures; its registration can be suspended or cancelled.
Regulator (CDSCO / DCGI)	Approves and inspects	Public-law accountability under Article 21; writ jurisdiction for regulatory failure.

Vicarious liability operates here in a way that complements what was discussed in the previous article. The hospital is vicariously liable where the investigator is its employee acting in the course of employment. A sponsor is regarded as responsible for what its CRO does on its behalf. **Direct liability** attaches to each party for its own failings: the sponsor for a defective protocol, the hospital for an inadequate facility, and the EC for a negligent approval.

In Lakshmi's case, the finger-pointing in Stage 5 is exactly what the framework is designed to prevent. The participant deals with the sponsor, and the allocation of blame among sponsor, CRO and hospital is their internal matter.

3.8 Wrongs in the research setting

Wrong	Explanation	Possible consequence
Enrolment without valid consent	Includes forged consent, misleading information or exploitation of illiteracy	Battery in tort, violation of Rules, cheating (S. 318 BNS), disciplinary action
Violation of the protocol	Giving a non-approved dose, enrolling ineligible subjects	Regulatory penalty, suspension, negligence claim
Failure to report SAE	Delayed or concealed adverse event	Regulatory sanction, aggravates civil and criminal liability

Wrong	Explanation	Possible consequence
Breach of confidentiality	Disclosing identifiable data	Tort claim; privacy under Article 21; DPDP Act
Denial of compensation	Refusing or delaying statutory payment	Enforcement through writ and regulatory action
Data fabrication	Falsified results	Cheating, regulatory prosecution, loss of registration
Exploiting vulnerable groups	Enrolling children, the mentally ill or the poor without safeguards	Constitutional challenge, regulatory penalty

3.9 The remedies available to a participant

1. **Statutory compensation** under the NDCT Rules (no-fault).
2. **Civil suit** for damages in tort or contract, based on negligence, battery or breach of confidentiality.
3. **Writ petition** (Arts. 32 / 226) against regulatory failure, or against the State where public institutions are involved.
4. **Complaint to the regulator** (CDSCO) or ethics committee, which can suspend or cancel trials and EC registrations and prosecute under the Drugs and Cosmetics Act.
5. **Complaint to the State Medical Council or NMC** for professional misconduct.
6. **Criminal complaint** for cheating, causing hurt or causing death by negligence.

A trial participant is generally **not a "consumer" under the Consumer Protection Act, 2019** where no consideration is paid for the service, so the consumer forum is an uncertain route and the Rules' compensation mechanism is the more reliable one.

4. Landmark Case Laws and Official Reports

The Indian crisis and judicial intervention

- ***Swasthya Adhikar Manch, Indore v. Union of India*, W.P. (C) No. 33 of 2012**

(Supreme Court; orders of 2013). The Court took up the ***public interest petition*** on unethical trials, including trials conducted on vulnerable patients in Indore. It condemned the ***regulatory failure*** and treated the matter as one concerning the right to life. The Court directed, among other things, that approvals of new trials be scrutinised at the highest levels of the Health Ministry with expert committee advice, that trial approvals be reviewed, that the **audio-visual recording of the informed consent process** be introduced, and that the Union Government put in place a mechanism for compensation. This case is the ***foundation of the post-2013 regulatory architecture***.[3]

- ***Parliamentary Standing Committee on Health and Family Welfare, 59th Report (2012)*, on the functioning of CDSCO**,[4] and the **72nd Report (2013)**[5] on alleged irregularities in the conduct of HPV vaccine studies by PATH. These reports found serious ***regulatory lapses***, including conflicts of interest and consent deficiencies, and fed directly into the Supreme Court litigation and the legislative reforms.

- ***Report of the Prof. Ranjit Roy Chaudhury Expert Committee (2013).*** Its recommendations on ***regulation, ethics committees and compensation*** shaped the 2013 amendments and the later 2019 Rules.[6]

Consent, autonomy and bodily integrity

- ***Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1.** The leading Indian decision on ***informed consent***: valid consent requires disclosure of the nature of the procedure, its risks and alternatives. Its principles apply with greater force to experimental interventions.[7]

[3] (2013) 4 SCC 1, (2013) 13 SCALE 146
[4] Parliament of India, Rajya Sabha, Department-Related Parliamentary Standing Committee on Health and Family Welfare, *Fifty-Ninth Report on the Functioning of the Central Drugs Standard Control Organisation (CDSCO)* (2012).
[5] Parliament of India, Rajya Sabha, Department-Related Parliamentary Standing Committee on Health and Family Welfare, *Seventy-Second Report on Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India* (2013).
[6] Ministry of Health and Family Welfare, Gov't of India, Report of the Expert Committee to Formulate Policy and Guidelines on Approval of New Drugs, Clinical Trials and Banning of Drugs **32–40** (2013) (Chaired by Prof. Ranjit Roy Chaudhury).
[7] AIR 2008 SUPREME COURT 1385, 2008 AIR SCW 855, 2008 (2) ALL LJ 711, 2008 (2) AIR BOM R 354, (2008) 2 MAD LW 336, (2008) 1 RAJ LW 853, 2008 (2) SCC 1, (2008) 1 RECCIVR 525, (2008) 1 SCALE 442, (2008) 39 OCR 593, (2008) 2 PUN LR 213, (2008) 1 ICC 705, (2008) 1 CTC 392 (SC), (2008) 2 ACJ 747, (2008) 2 MAD LJ 662, (2008) 1 RECCRIR 670, (2008) 1 CPJ 56, 2008 (2) ALLMR (NOC) 41, (2008) 5 BOM CR 373

- ***Selvi v. State of Karnataka*, (2010) 7 SCC 263.** The Court held that involuntary narco-analysis, brain-mapping and polygraph tests violate Articles 20(3) and 21, recognising ***bodily integrity and mental privacy***. Its reasoning supports the principle that no one may be made a subject of scientific testing without ***voluntary, informed consent***.[8]

- ***Common Cause v. Union of India*, (2018) 5 SCC 1.** Dignity and autonomy under Article 21 include the ***right to refuse medical treatment***. This reinforces the participant's absolute ***right to withdraw***.[9]

Privacy and data

- ***Justice K.S. Puttaswamy v. Union of India*, (2017) 10 SCC 1.** Privacy is a fundamental right, covering bodily integrity and informational privacy. The decision grounds the protection of participants' health data.[10]

Health, State responsibility and the right to life

- ***Consumer Education and Research Centre v. Union of India*, (1995) 3 SCC 42.** The ***right to health and medical care*** is part of the right to life under Article 21.[11]

- ***State of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83.** The right to health includes the ***right to medical facilities***, reinforcing the State's duty to regulate medical practice.[12]

[8] AIR 2010 SUPREME COURT 1974, 2010 (7) SCC 263, 2010 AIR SCW 3011, 2010 (3) AIR KANT HCR 19, (2011) 2 BOMCR(CRI) 473, (2010) 3 ALLCRILR 605, (2010) 1 CRILR(RAJ) 510, (2010) 2 CURCRIR 311, (2010) 2 RAJ LW 1688, (2010) 46 OCR 457, (2010) 2 CRIMES 241, 2010 (3) SCC(CRI) 1, 2010 (4) SCALE 690, 2010 CRILR(SC MAH GUJ) 510, (2010) 2 RECCRIR 896, (2010) 2 MAD LJ(CRI) 908, 2010 CALCRILR 2 597, (2010) 3 ALLCRIR 2640, (2010) 2 DLT(CRL) 530, (2010) 2 GUJ LH 357, 2010 CRILR(SC&MP) 510, (2010) 4 SCALE 690, (2010) 2 ALD(CRL) 401

[9] AIR 2018 SUPREME COURT 1665, AIR 2018 SC (CIV) 1683, (2018) 3 MAD LJ 503, (2018) 4 SCALE 1, (2018) 1 CRIMES 184, (2018) 1 CURCC 448, 2018 (5) SCC 1, 2018 (2) KLT SN 47 (SC), 2018 (1) KCCR SN 65 (SC)

[10] AIR 2017 SUPREME COURT 4161, (2017) 6 BOM CR 78, AIR 2017 SC (CIV) 2714, (2017) 3 KER LJ 17, 2017 (10) SCC 1, (2017) 124 ALL LR 877, (2017) 10 SCALE 1, (2017) 4 CURCC 87, (2017) 6 MAD LJ 267, (2017) 5 ALLMR 686 (SC), (2018) 1 RECCIVR 398, 2017 (178) AIC (SOC) 1 (SC), 242 (2017) DLT 9 (CN)(SC), 2017 (3) KCCR SN 255 (SC), 2017 (4) KLT SN 1 (KER)

[11] 1995 AIR 922, 1995 SCC (3) 42, AIR 1995 SUPREME COURT 922, 1995 AIR SCW 759, 1995 LAB. I. C. 1368, (1995) 2 LABLJ 768, (1996) 2 LAB LN 1, 1995 LABLR 289, (1996) 1 MAHLR 475, (1995) 4 SCT 631, 1995 (3) SCC 42, 1995 SCC (L&S) 604, (1995) 2 COMLJ 31, (1995) 2 CURLJ(CCR) 45, 1996 HRR 266, (1996) 72 FACLR 479, (1995) 1 SCR 626 (SC), (1995) 1 JT 636 (SC)

[12] AIR 1997 SUPREME COURT 1225, 1997 (2) SCC 83, 1997 AIR SCW 1260, 1997 (2) SERVLJ 25 SC, 1997 (1) SCALE 135, (1997) 1 JT 416 (SC), (1997) 2 SERVLJ 25, 1999 (2) UPLBEC 81, (1997) 91 FJR 332, (1997) 3 LAB LN 262, (1997) 1 SCT 716, 1997 SCC (L&S) 294, (1996) 4 SCJ 391, (1997) 1 SCALE 135, (1997) 1

Professional and institutional liability (applied to research settings)

- ***Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.** The standard of care and the line between civil and criminal negligence ***apply to investigators as doctors***.[13]

- ***Spring Meadows Hospital v. Harjol Ahluwalia*, (1998) 4 SCC 39.** Hospital liability for the negligence of its staff, an authority for the ***vicarious liability of host institutions***.[14]

- ***Balram Prasad v. Kunal Saha*, (2014) 1 SCC 384.** The Court's approach to compensation, including the ***multiplier method***, provides a template for assessing damages in research-related death.[15]

5. Analysis: From Rulebook to Reality

India's regulatory text is considerably stronger than it was a decade ago. The difficulty lies in verification.

1. **Consent as ritual.** Audio-visual recording captures that a conversation occurred, not that the participant understood. Language barriers, illiteracy and a power imbalance

SERVLR 745, (1997) 1 SUPREME 546, (1997) 2 ESC 1351, (1999) 2 UPLBEC 81

[13] AIR 2005 SUPREME COURT 3180, 2005 AIR SCW 3685, 2005 CRILR(SC&MP) 2 667, (2005) 3 RAJ CRI C 753, (2005) 4 CTC 540 (SC), (2005) 122 DLT 83, 2005 CRILR(SC MAH GUJ) 2 667, (2005) 33 ALLINDCAS 1 (SC), 2005 (6) SLT 1, 2005 (8) SRJ 50, 2005 (3) CPJ 9.2, 2005 ALL MR(CRI) 2567, 2005 SCC(CRI) 1369, (2005) 6 JT 584 (SC), (2006) 2 JCR 184 (SC), 2005 (6) SCALE 130, 2005 (6) SCC 1, 2005 (2) CALCRILR 472, 2005 (4) CTC 540, 2005 (3) JKJ 5, 2005 (33) ALLINDCAS 1, (2005) 3 ALL WC 2756, (2005) 3 CPR 70, (2005) 2 BOMCR(CRI) 339, (2005) 85 DRJ 330, (2005) 4 EASTCRIC 169, (2005) 5 SUPREME 297, (2005) 4 JLJR 137, (2005) ACJ 1840, (2005) 53 ALLCRIC 251, (2005) 3 CHANDCRIC 19, (2005) 3 CRIMES 63, (2005) 4 ALLCRILR 1, (2005) 3 GUJ LR 2126, (2005) 3 KER LT 965, (2005) MAD LJ(CRI) 1077, (2005) 32 OCR 175, (2005) 4 PAT LJR 213, (2005) 3 RECCRIR 836, (2005) 5 SCJ 601, (2005) 3 TAC 716, (2005) 5 ANDHLD 52, (2005) 3 ALLCRIR 2257, (2005) 6 SCALE 130, (2005) 3 CURCC 189, (2003) 1 JCR 314 (JHA), 2005 (3) ANDHLT(CRI) 1 SC, (2005) 3 ANDHLT(CRI) 1, (2005) 3 CPJ 92, 2005 (2) ALD(CRL) 334

[14] AIR 1998 SUPREME COURT 1801, 1998 (4) SCC 39, 1998 AIR SCW 1590, 1998 (2) ALL CJ 992, (1998) 3 PUN LR 719, 1998 ALL CJ 2 992, (1997) 2 CPR 235, 1998 BRLJ 160, 1998 (1) CCJ 521, 1998 (2) SCALE 456, 1998 (3) ADSC 61, (1998) 2 SCR 428 (SC), 1998 (1) UJ (SC) 706, (1998) 3 ALLMR 136 (SC), (1998) 1 CTC 665 (SC), (1998) 2 COMLJ 228, 1998 CCJ 1 521, (1998) 1 LS 74, 1998 ADSC 3 61, (1998) WRITLR 448, 1998 (1) BLJR 755, 1998 (120) PUN LR 719, 1998 UJ(SC) 1 706, (1998) 2 JT 620 (SC), (1998) 2 MAD LW 38, (1998) 1 CHANDCRIC 189, (1998) WRITLR 424, (1998) 1 CPR 1, (1998) 2 ALL WC 1259, (1998) 2 SCALE 456, (1998) 2 EASTCRIC 827, (1998) 1 GUJ LH 643, (1998) 3 MAD LJ 63, (1998) 2 ORISSA LR 93, (1998) 2 RAJ LW 239, (1998) 3 SCJ 71, (1998) 29 CORLA 170, (1998) 3 SUPREME 183, (1998) 2 ICC 196, (1998) 33 ALL LR 48, (1998) 3 CIVLJ 811, (1998) 92 COMCAS 797, (1998) 1 CPJ 1, 1998 (2) KLT SN 25 (SC)

[15] AIRONLINE 2013 SC 528

between doctor and patient persist.

2. **Ethics committee independence.** Many ECs are hosted by the institution that stands to gain from the trial. Members are often overburdened and lack training, and there is limited public information on their deliberations.

3. **Compensation delays and disputes.** The "related to the trial" test invites argument, and the burden of navigating the process falls on poor and poorly informed participants.

4. **Under-reporting.** Participants who are not told that adverse events must be reported rarely complain, and those who profit from the trial are the first to know of harm.

5. **Vulnerable recruitment.** The poor, the less educated and those dependent on public hospitals are over-represented among participants, which is a justice problem.

6. **A statutory gap.** The framework lies in delegated legislation under the Drugs and Cosmetics Act; a statute designed for the quality of drugs rather than the rights of research participants. There is no dedicated statute that gives participants rights directly.

7. **Regulatory capacity.** Inspection of sites is limited by resources, and the regulator is both promoter and policeman of the industry.

8. **Emerging challenges.** Decentralised and digital trials, genomic data, artificial intelligence and biobanks raise consent and privacy questions the Rules only partly address.

A caution is needed in the other direction. Over-regulation without proportion may drive legitimate research abroad or discourage academic and public-interest trials. The aim is to ensure that research is safe and ethical, not to prevent it.

6. Suggestions

1. **A dedicated Clinical Research Act** that creates statutory rights for participants (to information, to withdraw, to compensation, to privacy), rather than leaving them to delegated rules under a drug-quality statute.

2. **Accreditation and independence of ethics committees**, including mandatory external

members, conflict-of-interest disclosures, training and the publication of decisions, with periodic audit.

3. **A consent quality test**, such as a short "teach-back" assessment recorded with the consent, in the participant's language, and an independent counsellor or patient advocate, in addition to the audio-visual record.

4. **Special protections for vulnerable groups**: enhanced review, prohibition on recruitment through the treating doctor, and community consultation before trials in tribal or low-literacy areas.

5. **A central compensation mechanism**, funded by mandatory sponsor contributions or insurance, so that participants are paid promptly and sponsors recover disputed amounts afterwards.

6. **An independent adjudication forum** for compensation disputes, with fixed timelines and legal aid for participants.

7. **A public, searchable SAE and compensation database**, integrated with CTRI, to promote transparency and enable detection of patterns.

8. **Risk-based inspection and whistleblower protection** for research staff and ethics members who report misconduct.

9. **Clear liability rules for CROs, hospitals and sponsors**, stating expressly that delegation does not dilute accountability and that the host institution owes a non-delegable duty to participants in its care.

10. **Post-trial access and benefit-sharing obligations**, so that participants and communities' benefit from the successful drug.

11. **Updated data governance** for genomic and digital trial data, aligned with the DPDP Act, with explicit consent for secondary use.

12. **Ethics education** for investigators and students that goes beyond compliance to the culture of research, and public awareness campaigns so that participants know their rights.

7. Conclusion

The central question of research ethics is deceptively simple: *how much may we ask of one person for the sake of others?* The law's answer is that we may ask a great deal, but only if the person is truly free to refuse, truly informed about what she accepts, protected by someone with no stake in the outcome, and promised that she will not bear alone the cost of any harm.

Indian law has moved a long way towards that answer. The Nuremberg and Helsinki principles have been absorbed into the ICMR Guidelines and the NDCT Rules. The no-fault compensation scheme reflects the view that those who profit from research must bear its risks. The Supreme Court, in *Swasthya Adhikar Manch*, made clear that the exploitation of the vulnerable in the name of science is a constitutional wrong, not just a regulatory lapse.

Yet the final test is not the text of the rules but the experience of someone like Lakshmi. Was the form read to her, and did she understand it? Was the committee that approved the protocol independent, and did anyone ask whether the placebo was fair? When she fell ill, was the event reported and was she compensated promptly, without having to prove anything? Where the answers are yes, clinical research earns the trust on which it depends. Where they are no, no amount of scientific progress can justify the cost, because a medicine that is discovered by treating people as means alone has already failed ethically.