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Informed consent to clinical research in India: A private law remedy

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journals.sagepub.com/home/mlj**Himani Bhakuni** 

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Abstract

There is a well-established common law doctrine for ascertaining information disclosure in informed consent claims within the treatment context that governs the doctor–patient relationship. But there is no such doctrine in clinical research governing the researcher–participant relationship in India. India, however, is not exceptional in this regard. Common law countries like the United States and Canada at most have sparse, non-systematised, criteria for such cases; arguably, a doctrine for research is at its nascent stage. But the adequacy of the existing criteria for settling informed consent claims in research has hardly ever been discussed. Furthermore, a specific discussion on the applicability of this ‘nascent doctrine’ to India is non-existent. This article discusses both. The article examines case law from India and other common law jurisdictions that hint at developments in this area. It suggests that Indian courts need to move abreast with other jurisdictions to better protect India’s patients and research participants.

Keywords

India, informed consent, legal doctrine, common law, protection of research participants, health research, clinical trials

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Introduction

India’s research industry has been subject to increased scrutiny, precipitated by numerous incidents of unethical trials being reported in the national and international media. The alleged victims of these trials either did not consent to participate in these trials at all

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or gave inadequate consent. Most of the research studies that were under scrutiny had been given ethical clearance to proceed, but the procedure of consent post-clearance was found to be deficient.¹ No substantial remedial steps, except suspension of some trials, were taken. Yet, could these victims claim a remedy in court under private law? Some might be quick to assume that there is a clear legal answer to this question, but there is not.

There is well-established common law doctrine for establishing the adequacy of information disclosure in informed consent claims within the treatment context that governs the doctor–patient relationship. But there is no such doctrine in clinical research governing the researcher–participant relationship. India, however, is not exceptional in this regard. Common law countries like the United States and Canada have, at best, sparse, non-systematised criteria for such cases; arguably, a doctrine of informed consent for research is at a nascent stage. But the adequacy of the existing criteria for resolving informed consent claims in research is rarely discussed. Furthermore, a specific discussion on the applicability of this ‘nascent doctrine’ to India is non-existent. This article examines both of these issues.

The article is divided into four parts. The first section briefly outlines the clinical research context and regulation pertaining to informed consent in India and explains the relevance of the article. The second section gives an overview of the current Indian precedent dealing with the lack of informed consent within the treatment context. It also considers the feasibility of its applicability to the research context. Due to the absence of case law on the lack of informed consent in research in India, the third section engages in a normative discussion on how an Indian legal doctrine of informed consent in treatment can be developed around clinical research. This is based on an analysis of case law from other common law jurisdictions. The fourth section discusses the limits of law in dealing with informed consent in research within the larger social context of India.

Framing the issue

India became one of the preferred destinations for globalised clinical trials because conducting a trial in India can potentially reduce the cost of trial by up to 60% due to cheap labour, low infrastructure costs and easier access to participants.² In the early 2000s, with increasing policy support from the Indian government, the global pharmaceutical industry became interested in moving its trial operations to India.³ In 2005, the

1. This problem, however, is commonplace and not simply restricted to the publicised cases of unethical trials. In a 2016 survey that aimed to assess the quality of ethics of clinical research processes in India, the surveyors found that even if the average informed consent document used in research was to be designed as per the regulatory requirements, it was unlikely to produce the level of ‘informed consent as ethically required’. M. Patel et al., ‘Informed Consent Document and Process in India: Ethical and Quality Issues’, *Asian Bioethics Review* 8 (2016), pp. 37–52.
2. G. Sinha, ‘Outsourcing Drug Work: Pharmaceuticals Ship R&D and Clinical Trials to India’, *Scientific American* 291 (2004), pp. 24–25.
3. V. Bajpai, ‘Rise of Clinical Trials Industry in India: An Analysis’, *International Scholarly Research Notices: Public Health* 13 (2013).

government amended Schedule Y of the Drugs and Cosmetics Rules 1945, appended to the Drugs and Cosmetics Act 1940. This statute regulates the import, manufacture, distribution and sale of drugs and cosmetics in India. The amendment of Schedule Y in 2005 established the guidelines for the conduct of clinical trials in the country.⁴ Provisions were made in the Schedule to ensure that patients and volunteers participate in studies only after a complete and proper understanding of the investigative study. An elaborate informed consent process, along with the responsibilities of Institutional Ethics Committees, clinical investigators and trial sponsors, was outlined in Schedule Y.

To complement Schedule Y, the Indian Council of Medical Research (ICMR), the apex body for the formulation, coordination and promotion of biomedical research in India, updated the ethical guidelines for human subject research in 2006, which were first released in 2000 and updated again in 2017.⁵ India adopted the Good Clinical Practice (GCP) guidelines (originally released by the International Conference on Harmonisation) in 2001; these guidelines prescribe the ethical and scientific quality standards for designing, conducting and recording trials that involve the participation of human subjects.⁶ The GCP guidelines lay down an elaborate consent process that is expected to be followed by researchers.⁷ Despite being the primary sources for governing the ethics of clinical research in India, the ICMR and GCP guidelines lack enforceability. Failures to adhere to guidelines, at the most, lead to either suspension of trial or disciplinary hearings.⁸ Schedule Y is the lone legal source that makes informed consent mandatory for clinical research in India. However, it does not specify the repercussions for failure to

4. Schedule Y was introduced in the year 1988 to support the growth of the generic Indian pharmaceutical industry. At the time, it only permitted clinical trials at a phase lower than the global status. The Schedule was later amended (in 2005) to remove the Phase lag, which meant that phase II to III trials could be carried out concurrently, which facilitated the growth of global clinical development programmes in India. The Schedule was also amended to make it compliant with the International Conference on Harmonisation-Good Clinical Practice guidelines, thereby introducing guidelines related to informed consent procedures. See A. Bhatt, 'Evolution of Clinical Research: A History Before and Beyond James Lind', *Perspectives in Clinical Research* 1 (2001), pp. 6–10. See also Amendment, Drugs and Cosmetic Rules of 1945, Schedule Y, vide Subs. G.S.R. 32(E), dated 20 January 2005. Available at: http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf (accessed 2 May 2020).
5. Indian Council of Medical Research, Ethical Guidelines on Medical and Health Research on Human Participants, 2017. Available at: https://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf (accessed 2 February 2020).
6. Central Drugs Standard Control Organization (CDSCO), Good Clinical Practice Guidelines (GCP guidelines). Available at: <http://www.cdsco.nic.in/html/GCP1.html> (accessed 2 May 2020).
7. Op. cit., section 2.4.3. 'Informed Consent Process'.
8. These two recourses have been rarely employed by the governing bodies. Suspensions took place only when the cases of unethical trials were publicised (e.g. Indore and human papilloma virus vaccine case) and disciplinary proceedings were held for trial investigators who were registered doctors and governed under Indian Medical Council Act 1956 (e.g. Indore and Bhopal trials). Both avenues still leave individual victims of lack of informed consent in research without a suitable remedy.

observe the procedures therein. This lack of penalty for failure to take (adequate) informed consent from participants in research has led to abuse.⁹ So much so that in response to the Supreme Court's inquiry into why the government failed to take action against unethically conducted foreign-sponsored trials in 2015,¹⁰ the government acknowledged that '[a]s of now, there are no specific penalties for provisions relating to clinical trials under the [Drugs and Cosmetics] Act'.¹¹

To chart a brief history of unethical clinical research in India, before 2005, one finds only a few documented instances of research conducted without the informed consent of research subjects in India.¹² However, post 2005, after the sudden growth of the clinical research industry,¹³ numerous commentators started alleging regulatory problems in clinical trial regulation in India and casting doubt over the ethics of some of the trials.¹⁴ A number of incidents of trials with inadequate or no consent from participants came to be reported in the Indian and the international media between the years 2000 and 2010.¹⁵ Chief among them were the Indore trials,¹⁶ trials involving Bhopal Gas Tragedy victims¹⁷

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9. See further S. Nundy and C.M. Gulhati, 'A New Colonialism? – Conducting Clinical Trials in India', *The New England Journal of Medicine* 352 (2005), pp. 1633–1636.
 10. *Kalpna Mehta & Ors. v. Union of India & Others*, W. P. (Civil) 558/2012.
 11. U. Anand, 'Can't Penalise US NGO for Violating Drug Trial Norms', *The Indian Express* 18 April 2015.
 12. Like the Letrozole Trials in which a drug to induce ovulation was tested on about 400 women without their knowledge or consent. More examples can be found in the SOMO briefing paper on ethics in clinical trials, 'Examples of unethical trials' (February 2008). Available at: https://www.wemos.nl/wp-content/uploads/2016/07/examples_of_unethical_trials_feb_2008.pdf (accessed 2 May 2020); see also C.M. Gulhati, 'Needed: Closer Scrutiny of Clinical Trials', *Indian Journal of Medical Ethics* 12 (2004), pp. 4–5.
 13. India became compliant with The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005. R. Jeffery et al., 'Big-Pharmaceuticalisation: Clinical Trials and Contract Research Organisations in India', *Social Science & Medicine* 131 (2015), pp. 239–246, 240.
 14. S. Chattopadhyay, 'Guinea Pigs in Human Form: Clinical Trials in Unethical Settings', *The Lancet* 379 (2012), p. e53; G. Vaidyanathan, 'Failings Exposed at India's Drug Regulator', *Nature* 18 May 2012; A. Raju, 'Indian Regulatory System Needs to Be Strengthened to Improve Clinical Trial Industry in India: Neuland Labs CFO', *PharmaBiz* 23 December 2014.
 15. A. Buncombe and N. Lakhani, 'Without Consent: How Drugs Companies Exploit Indian 'Guinea Pigs'', *The Independent* 14 November 2011; S. Lloyd-Roberts, 'Have India's Poor Become Human Guinea Pigs?' *BBC News* 1 November 2012; Al Jazeera (Documentary), *Outsourced: Clinical Trials Overseas*, *Fault Lines AJ*. Available at: <http://www.aljazeera.com/programmes/faultlines/2011/07/2011171112453541600.html> (accessed 2 February 2020).
 16. V. Krishnan, 'MP Govt to Act Against 11 Indore Doctors', *Live Mint* 22 October 2012. Available at: <http://www.livemint.com/Politics/NxmwzRufEq2Efjcl888OFJ/MP-govt-to-act-against-11-Indore-doctors.html> (accessed 2 May 2020).
 17. N. Lakhani, 'From Tragedy to Travesty: Drugs Tested on Survivors of Bhopal', *The Independent* 15 November 2011. Available at: <http://www.independent.co.uk/news/world/asia/from-tragedy-to-travesty-drugs-tested-on-survivors-of-bhopal-6262412.html> (accessed 20 May 2020).

and the human papilloma virus vaccine (*Gardasil* and *Cervarix*) trial.¹⁸ Some commentators called the practice of trials in India by foreign pharmaceuticals and research centres ‘the new colonialism’.¹⁹ The public outrage over the allegedly unethical trials culminated in a Public Interest Litigation (PIL).²⁰

In 2012, prompted by a series of unethically conducted trials reported in the media, the non-government organisation (NGO) ‘Swasthya Adhikar Manch’ (Health Rights Forum) filed a petition in the Supreme Court of India. The PIL titled *Swasthya Adhikar Manch v. Union of India*²¹ (*SAM* case) was brought before the Supreme Court of India asking the Court to intervene in the matter of illegal and unethical trials being conducted on adults, children and mentally ill people in the country. The interim orders of the Supreme Court in this case have led to an overhaul in the legal and regulatory provisions related to the conduct of clinical trials in the country.²² In 2013, after hearing the *SAM* case, the Supreme Court observed that the ‘uncontrolled’ clinical trials of drugs on human subjects by multinational companies were wreaking ‘havoc’ in the country, noting that the government had slipped into ‘deep slumber’ regarding this ‘menace’.²³ The interim orders of the Supreme Court²⁴ made the Central Drugs Standard Control Organization (CDSCO), which is the national regulatory body for Indian pharmaceuticals and medical devices, issue a notification making audio–video recording (AVR) of informed consent proceedings during trials mandatory for all clinical trials.²⁵ The

18. The case also led to official government inquiry into the alleged irregularities. Parliament Standing Committee, Rajya Sabha Report No. 72 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 (Department of Health Research, Ministry of Health and Family Welfare), August 2013/Bhadra, 1935 (Saka). Available at: <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/72.pdf> (accessed 2 May 2020).

19. Nundy and Gulhati, ‘A New Colonialism?’.

20. In Public Interest Litigation (PIL), the *locus standi*, that is, the eligibility of a person and the procedures to invoke the jurisdiction of the appellate courts (Supreme Court of India & the High Courts of the States) are so relaxed that anyone asserting a violation of a fundamental right can file a claim in one of the appellate courts. Even letters and telegrams addressed to the Court in violation of a fundamental right have been entertained as PIL’s. However, letters and petitions have to establish a claim of violation of a fundamental right and should not be for pecuniary or other gain (in essence, must not be frivolous litigation). See Supreme Court of India, Compilation of Guidelines To Be Followed For Entertaining Letters/Petitions Received. Available at: <http://supremecourtindia.nic.in/circular/guidelines/pilguidelines.pdf> (accessed 2 May 2020).

21. W. P. (Civil) No. 33 of 2012.

22. The case is *sub judice*.

23. Report, ‘SC Raps Govt Slumber on Illegal Clinical Trials’, *The New Indian Express* 4 January 2013. Available at: <http://newindianexpress.com/nation/article1406966.ece> (accessed 2 May 2020).

24. The status of a pending or disposed of case by the Supreme Court of India, including all interim orders can be found at <http://judis.nic.in/supremecourt/chejudis.asp> (accessed 20 May 2020).

25. Directorate General of Health Services (DCGI), Order Number: F. No. GCT/20/SC/Clin./2013/DCGI (19 November 2013). Available at: <http://www.cdsc.nic.in/writereaddata/Office%20Order%20dated%2019.11.2013.pdf> (accessed 20 May 2020).

audio–video requirement for informed consent was later restricted to only ‘vulnerable subjects’,²⁶ but the notification did not carry a definition for vulnerable subjects. Moreover, the regulatory bodies decided that to protect the privacy of the participants in anti-human immunodeficiency virus or anti-leprosy drug trials, only audio (and no video) recording of consent would be required.²⁷

In the aftermath of the *SAM* case, clinical research in India is still governed under the Drugs and Cosmetics Act, 1940. However, an amended Schedule Y has introduced the requirement to make an AVR of informed consent mandatory for vulnerable subjects. Some guidelines were released by the CDSCO on how AVR is to be done to comply with rules regarding privacy and confidentiality of the research subjects.²⁸ However, there is ambiguity surrounding the vetting of the consent tapes and the definition of vulnerable subjects. Post the *SAM* case, new regulations pertaining to the conduct of trials were released, which led to a brief lull and a negative impact on the growth of the clinical research industry.²⁹ As things stand in 2020, no strict penalties have been introduced for the violation of ethical guidelines during the conduct of research, not even for violation of the legally mandated procedure for obtaining informed consent.

This background leads one to question the role of law in providing a suitable remedy to the victims of lack of informed consent in research. While informed consent is widely accommodated under tort law, the *SAM* case demonstrates a process – which is now considered a trend in India³⁰ – of constitutionalisation of private law. Before diving into the private law remedy for a lack of informed consent in treatment and research, I will first address why a constitutional approach to this problem does not suffice in providing an adequate remedy to victims of a lack of informed consent in research.

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26. A study among a rural community studying the willingness of participants to be recorded during the consent process found that more than one-third of the participants refused to be video-taped, see R. C. Chauhan et al., ‘Consent for Audio-video Recording of Informed Consent Process in Rural South India’, *Perspectives in Clinical Research* 6 (2015), pp. 159–162; S. Nadimpally and D. Bhagianadh, “‘The Invisible’’: Participant’s Experiences in Clinical Trials’, *Perspectives in Clinical Research* 8 (2017), pp. 5–10.
 27. Ministry of Health and Family Welfare, Gazette Notification G.S.R. 611/(E), (31 July 2015). Available at: <http://www.ferci.org/wp-content/uploads/2014/07/Gazette-Notification-31-July-2015-AV-consent.pdf> (accessed 2 May 2020).
 28. Central Drugs Standard Control Organisation, Draft Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trials, Guidance Document (9 January 2014). Available at: http://www.cdsc.org.in/writereaddata/Guidance_for_AV%20Recording_09_January.14.pdf (accessed 2 May 2020).
 29. A. Nair, ‘Clinical Research: Regulatory Uncertainty Hits Drug Trials in India’, *Pharmaceutical Journal* 12 March 2015; for an overview of what the current regulatory scene is and what could be expected in the future, see A. Bhavne and S. Menon, ‘Regulatory Environment for Clinical Research: Recent Past and Expected Future’, *Perspectives in Clinical Research* 8 (2017), pp. 11–16.
 30. S. Balganes, ‘The Constitutionalization of Indian Private Law’, *Penn Law Faculty Scholarship Paper* 1557 (2016).

The constitutional approach and its limitations

If we frame informed consent within the narrative of constitutional rights, a research participant's right to informed consent can broadly be placed under the right to autonomy. The Constitution of India provides for the protection of 'personal liberty' under Article 21, which also includes protection of personal autonomy. The Supreme Court has held personal liberty and autonomy to include 'both the negative right not to be subject to interference by others and the positive right of individuals to make decisions about their life, to express themselves and *to choose which activities to take part in*'.³¹ Constitutional rights are usually enforceable by an individual vertically against state authorities.³² But constitutional courts in different jurisdictions have allowed for the application of rights horizontally, which means that an individual may enforce constitutional rights against non-state private bodies.³³ I make this point to suggest that if a claim based on the violation of the right to informed consent were brought before the courts³⁴ in India, as a violation of right to life and personal liberty, it would, in the first instance, only be maintainable against state actors.³⁵ However, the Supreme Court could impose an obligation upon the state to take necessary steps to ensure the observation of fundamental rights by other private individuals.

If horizontality is applied,³⁶ which the Supreme Court has shown an inclination towards but not quite fully endorsed for some rights,³⁷ the enforcement of fundamental

31. *Anuj Garg v. Hotel Association of India* (2008) 3 SCC 1, ¶34-35 (My emphasis).

32. Article 12, Constitution of India 1949 provides that '[s]tate includes the Government and Parliament of India and the Government and the Legislature of each of the States and all local or other authorities within the territory of India or under the control of the Government of India'.

33. See S. Gardbaum, 'The "Horizontal Effect" of Constitutional Rights', *Michigan Law Review* 102 (2003), pp. 388–459.

34. In India, the High Courts of various states and the Supreme Court have the jurisdiction to hear cases on violation of fundamental rights. See S. Choudhary et al., eds., *Oxford Handbook of the Indian Constitution* (Oxford: Oxford University Press, 2016).

35. Unless otherwise the claimants could prove that the body they brought the claim against was so close to a state body in structure and function that it be regarded as 'state' for purposes of enforcement of fundamental rights. As far as maintainability of such a claim is concerned, it could fall under a tort claim of suing the state via vicarious liability. The Supreme Court has recognised in *State of Rajasthan v. Vidyawati*, AIR 1962 SC 933, that State is liable for the tort or wrongs committed by its officials. Moreover, in *Rudal Shah v. State of Bihar*, AIR 1983 SC 1086, the court held that the violation of right to life and personal liberty could end in civil liability.

36. The Supreme Court has applied horizontality by including certain private bodies under 'other authorities', these bodies, to be considered 'state', ought to resemble state bodies in either their 'structure' or 'function' and should be closely connected to the State. Fundamental rights are generally regarded as *negative* rights; this means that they cast some constraints upon the actions of the State. They normally do not impose *positive obligations* upon the State to act in a particular way. However, the Supreme Court of India has imposed positive obligations upon the State to regulate acts of private individuals. This could be regarded as an application of horizontality through imposition of positive obligations. See G. Bhatia, 'Horizontality Under the Indian Constitution: A Schema', *Indian Constitutional Law and Philosophy Blog* 24 May 2015. Available at: <https://indconlawphil.wordpress.com/2015/05/24/horizontality-under-the-indian-constitution-a-schema/> (accessed 15 May 2020).

37. Op. cit.

rights could perhaps, someday, be directly extended to private non-state actors. As for now, the remedial avenue available by invoking fundamental rights enshrined in the Constitution of India is twofold – (X) to plead a writ against the state³⁸ or (Y) demand compensation from a government official, who in the process of doing his or her official duty violated a right that harmed the individual.³⁹

The first avenue, (X), was chosen by the petitioners in the *SAM* case. It must be noted that a violation of informed consent norms was not the sole cause of action in the *SAM* case and the petitioners sought a writ, in the public interest, against the state bodies.⁴⁰ It remains to be seen what a court would do where an *individual* (or a single person's) petition claims a violation of the right to life due to a lack of informed consent in clinical trial participation. The court could, and probably might, direct the state to take steps towards controlling further violation of fundamental rights. Under the second avenue, (Y), damages can be claimed by a broader application of tort law against the state (via vicarious liability). But such a claim would require the proof that the violator was performing an act in official capacity, in the employment of the state, and the act in such capacity violated the fundamental right of the individual which led to harm or injury.⁴¹ This claim would be impossible to bring in a clinical trial organised and executed entirely by private actors. (Y) would only be possible in a government-run (or government-sponsored) trial or where an investigator was working in the capacity of an employee of the state.

Avenues (X) and (Y) are both unsuitable to trials that are conducted by private or foreign actors and also unsuitable for *individual* victims of lack of informed consent in research. Given that the constitutional approach is inadequate, we should favour the tort law option which already has a decent corpus of case law on informed consent. To further this claim, in the next section, I will analyse the current leading precedent on informed consent to treatment in India and extrapolate its application to the research context.

Law of informed consent in treatment

Here I will analyse how informed consent is understood in tort law in India. Other than the Consumer Protection Act 1986 (CPA), where doctors are treated as *service providers* and patients as *consumers* of such services and the lack of informed consent as a *deficiency in service*, there is no other statutory basis for a lack of informed consent claim in treatment.⁴² The standards for information disclosure as developed in the torts

38. Article 32 (Supreme Court) & Article 226 (High Courts), Constitution of India.

39. National Commission to Review the Working of the Constitution, 'A consultation paper on: Liability of the State in Tort' (8 January 2001). Available at: <http://lawmin.nic.in/ncrwc/finalreport/v2b1-13.htmv> (accessed 2 May 2020).

40. And therefore, not private 'individual' interest.

41. Article 300, Constitution of India, provides for the State to be sued as juristic personality. But for a tortious action brought against the state for the act of its servants, the three elements that must be present. See generally J.W. Neyers, 'A Theory of Vicarious Liability', *Alberta Law Review* 43 (2005), pp. 287–326.

42. Consumer Protection Act 1986, s. 2(d) for consumer, s. 2(g) for deficiency of service and s. 2(o) for service. Furthermore, some states in the United States and Canada have specific

of medical negligence and battery form the corpus of the legal doctrine of informed consent.

In private law, a doctor can be liable for negligence if she fails in her duty to disclose the material risks inherent in the proposed therapeutic treatment or surgery and damage results from the failure to disclose.⁴³ Thus, the patient has the common law right to recover damages against the physician for failure to provide adequate informed consent.⁴⁴ Lack of informed consent cases may also fall under the torts of trespass to persons, namely, the tort of ‘battery’ in India. Most torts fall under two categories – intentional and unintentional torts.⁴⁵ To put it simply for the purposes of this article, negligence is an unintentional tort which can apply where a patient is not sufficiently informed about the risks inherent in the treatment and/or alternatives to the treatment, whereas battery is an intentional tort where the doctor intended to cause contact (touching) with the patient without the patient’s consent.⁴⁶ Thus, in order for a tort of battery to be established two conditions must be met, viz., (i) intentional unauthorised contact with the patient (trespass to person) and (ii) lack of patient’s consent. It is pertinent to note that ‘harm’ is not a necessary condition for an action under battery. A patient can recover for battery even if she is not harmed, provided that the doctor performs the medical intervention without the patient’s consent.⁴⁷ It is important to note the difference between these torts because there have been situations where a claim was erroneously identified under battery instead of negligence.⁴⁸ This often leads to dismissal of the case for inappropriate cause of action.

Indian case law on informed consent in treatment

The leading authority on informed consent in the medical treatment context in India is *Samira Kohli v. Dr. Prabha Manchanda & Another*.⁴⁹ Samira Kohli, the petitioner,

statutes that deal with lack of informed consent in treatment, see, for example, Ontario’s Health Care Consent Act 1996, Louisiana’s Medical Malpractice Act 1975 and so on.

43. Winfield, whose text-book might be well-known among tort law students in India and abroad, notes that a “tortious liability arises out of breach of duty primarily fixed by the law: this duty is towards persons generally and its breach is redressible by an action for unliquidated damages”. See P.H. Winfield, *A Text-book of The Law of Tort* (London: Sweet & Maxwell, 1954); See also V.G. Koch, ‘A Private Right of Action for Informed Consent in Research’, *Stetson Hall Law Review* 45 (2015), p. 174.

44. Op. cit.

45. See N.J. Moore, ‘Intent and Consent in the Tort of Battery: Confusion and Controversy’, *American University Law Review* 61 (2012), pp. 1585–1654.

46. The tort of battery can be defined as a ‘direct act of the defendant which has the effect of causing contact with the body of the plaintiff without the latter’s consent’. F.A. Trindale, ‘Intentional Torts: Some Thoughts on Assault and Battery’, *Oxford Journal of Legal Studies* 2 (1982), pp. 211–237, 216.

47. D.B. Dobbs, *Dobbs’ Law of Torts*. 2nd ed. (Eagan: West, 2014).

48. *Chatterton v. Gerson* [1981] Q.B. 432; *Reibl v. Hughes* [1980] 2 SCR 880.

49. *Samira Kohli v. Dr. Prabha Manchanda and Another* (2008) 2 SCC 1. Available at: <https://indiankanoon.org/doc/438423/> [paragraph numbers correspond to the web print version] (accessed 2 May 2020).

consulted with Dr. Prabha Manchanda, the respondent, regarding her prolonged menstrual bleeding. She was admitted to the respondent's clinic where she signed the consent form for hospital admission, medical treatment and for surgery. The consent form for surgery described the procedure to be undergone by the petitioner as 'diagnostic and operative laparoscopy. Laparotomy may be needed'.⁵⁰ The petitioner was subjected to a laparoscopic examination under general anaesthesia. While the petitioner was unconscious during her examination, the respondent's assistant took the consent of the patient's mother for a hysterectomy. After this, the respondent removed the patient's uterus (abdominal hysterectomy), ovaries and fallopian tubes (bilateral salpingo-oophorectomy). The petitioner filed a complaint before the National Consumer Disputes Redressal Commission (NCDRC) under the CPA, claiming compensation of INR 25 lakh⁵¹ from the respondent. Her complaint alleged that the doctor had been negligent and that the radical surgery, by which her uterus, ovaries and fallopian tubes had been removed, had been performed without her consent. The petitioner claimed compensation for the loss of her reproductive organs, irreversible damage to the body, loss of the opportunity to become a mother, diminished prospects of matrimony and emotional trauma. The NCDRC dismissed the complaint on the grounds that the hysterectomy had been performed with adequate care and that the patient had voluntarily sought treatment at the respondent's clinic. Aggrieved by the order, the petitioner filed an appeal in the Supreme Court of India. The court overruled the order passed by the NCDRC and held that:

... there was no consent by the appellant for performing hysterectomy and salpingo-oophorectomy, performance of such surgery was an unauthorized invasion and interference with appellant's body which amounted to a tortious act of assault and battery and therefore a deficiency in service.⁵²

The court, however, observed that even though the respondent's act was in 'excess of consent',⁵³ the act was done in *good faith* and for the benefit of the petitioner. Consequently, the compensation that was directed to be paid to the petitioner was significantly less than claimed.⁵⁴ The following examines the relevance of this case to the research context.

50. Op. cit.

51. A lakh is a unit of hundred thousand (100,000).

52. *Kohli* at [54].

53. Meaning acts performed in excess of what was consented to or acts involving consent to only the partial procedure instead of the whole.

54. The petitioner was denied the entire fee charged for the surgery and was directed to pay INR 25,000 as compensation for the unauthorised abdominal hysterectomy and bilateral salpingo-oophorectomy surgery to the appellant.

Importance of the Kohli case and its applicability to the research context

Adequate disclosure of information is one of the essential elements of informed consent.⁵⁵ Courts in different common law jurisdictions use three distinct standards to assess information disclosure – the *professional practice standard*, the *reasonable person standard* and the less commonly used *subjective standard*.⁵⁶ The *Kohli* case dealt with two of these standards: the professional practice standard, also known as the *Bolam* test, and the reasonable person standard, called the *Canterbury* principle. Let us briefly review these standards before evaluating the *Kohli* case.

The US Courts of Appeals, District of Columbia Circuit's decision in *Canterbury v. Spence*⁵⁷ laid down the 'reasonable person standard', also called the *Canterbury* principle, which mandated the doctor to disclose all 'material risks' to a patient to indicate that the consent was 'informed'. The US court held that:

[t]rue consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.⁵⁸

Thereafter, the court laid down that the doctors had a duty to disclose all material risks to the patient with the exception of where disclosure of risks would pose a threat to the well-being of the patient. The court also defined 'material' risk, holding that a risk was material:

... when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.⁵⁹

The 'professional practice standard' for determining negligence and for assessing information disclosure was applied in the UK case, *Bolam v. Friern Hospital Management Committee*.⁶⁰ Here, Justice McNair, giving his direction to the jury, stated:

55. The others being voluntariness and capacity to consent. See R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), p. 155.

56. Faden and Beauchamp, p. 305. The subjective patient standard would require the physician to disclose whatever information is material to the particular patient.

57. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972). In this case, the plaintiff, Canterbury, claimed that prior to his spinal surgery, the defendant, surgeon Spence, did not disclose the probable consequence of paralysis which the plaintiff later developed as a result of the surgery.

58. Op. cit. at [780]

59. *Canterbury* at [787].

60. *Bolam v. Friern Health Management Committee* [1957] 1W.L.R. 582 (QB).

[A doctor] is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art.⁶¹

The wording of this direction came to be known as the *Bolam* test and for some time was treated as applicable to a doctor's duty to disclose the risks of proposed treatment.⁶²

The English courts have now moved beyond the *Bolam* test. In a 2015 case, *Montgomery v. Lanarkshire Health Board*,⁶³ the UK Supreme Court, while deciding on the issue of whether a consultant obstetrician and gynaecologist was negligent in managing the pregnancy of Mrs. Montgomery, made way for a fresh legal understanding of the concept of informed consent. The seven Judge Bench allowed Mrs. Montgomery's appeal after a careful analysis of the post-*Bolam* cases on informed consent. Following *Montgomery*, the *Bolam* test would no longer apply to disclosure for consent as it has been replaced with a more patient-centred test.⁶⁴ This means that, in the UK, the standard has shifted from the paternalistic 'what a reasonable practitioner would do' to a patient-autonomy enhancing 'what a reasonable person would want to know'. *Montgomery's* implications for the research context and on the doctrine of informed consent in India will be addressed in the fourth section. But first this article analyses the *Kohli* judgment evaluating its suitability as a benchmark to decide future cases arising from a lack of informed consent in research.

Kohli, Bolam and India

The contribution of the *Kohli* case to the jurisprudence on informed consent in India is noteworthy for two reasons: (1) it rejects the *Canterbury* principle, or the reasonable person standard, for information disclosure and (2) it adopts a socio-economic line of reasoning to prefer the *Bolam* test over *Canterbury*. The judges in this case noted:

In India, [the] majority of citizens requiring medical care and treatment fall below the poverty line. Most of them are illiterate or semi-literate. *They cannot comprehend medical terms, concepts, and treatment procedures.* They cannot understand the functions of various organs or the effect of removal of such organs. They do not have access to effective but costly diagnostic procedures. Poor patients lying in the corridors of hospitals after admission for want of beds or patients waiting for days on the roadside for an admission or a mere examination, is a common sight. For them, any treatment with reference to rough and ready diagnosis based on their outward symptoms and doctor's experience or intuition is acceptable and welcome so long as it is free or cheap; and whatever the doctor decides as being in their interest, is usually unquestioningly accepted. *They are a passive, ignorant and uninvolved in treatment procedures.*⁶⁵ (My emphasis)

61. Op. cit. at [587]

62. *Sidaway v. Governors of Bethlem Royal Hospital* [1985] AC 871.

63. [2015] UKSC 11.

64. See J. Badanoch QC, 'A Doctor's Duty of Disclosure and the Decline of 'The Bolam Test': A Dramatic Change in the Law on Patient Consent', *Medico-Legal Journal* 84 (2016), p. 12.

65. *Kohli* at [26].

This line of reasoning, where poverty and poor conditions of literacy are automatically assumed to render an individual ‘passive’ and ‘ignorant’ about one’s treatment decisions, is dangerously paternalistic. Although the judges in the *Kohli* case have shown great awareness and sympathy for the *real* conditions of patients in India, they have reiterated the support for paternalism that the *Bolam* test seemed to exemplify with its ‘doctors know best’ approach.⁶⁶ While making observations about the appalling conditions of patients in India, the judges in this case also questioned the relevance of informed consent in a country like India. They opined:

The poor and needy face a hostile medical environment inadequacy in the number of hospitals and beds, non-availability of adequate treatment facilities, utter lack of qualitative treatment, corruption, callousness and apathy. Many poor patients with serious ailments (e.g. heart patients and cancer patients) have to wait for months for their turn even for diagnosis, and due to limited treatment facilities, many die even before their turn comes for treatment. What choice do these poor patients have? Any treatment of whatever degree, is a boon or a favour, for them. *The stark reality is that for a vast majority in the country, the concepts of informed consent or any form of consent, and choice in treatment, have no meaning or relevance.*⁶⁷ (My emphasis)

The conclusion of the Court here is problematic on at least two grounds. First, informed consent is not a conditional right. Holding that informed consent has ‘no meaning or relevance’ for the poor owing to the lack of treatment facilities implies that informed consent is a *luxury* afforded to those who are not poor and have access to medical facilities. Yet all patients and research participants, whether rich or poor, have the right to be informed about the treatment or study and have the right to either consent or not consent depending on that information. Second, the judges in this case lost an excellent opportunity to reaffirm the duty of care owed to patients irrespective of their backgrounds. Even though the premise of the entire paragraph is true and shows that the judges are aware of the ground realities in India, the conclusion ought to have been in favour of the protection of every patient’s autonomy. If this reasoning were to be extended to the research context, it would not stand, as no one would condone a position that informed consent has no meaning or relevance for the poor people volunteering for clinical research. In fact, the situation is quite the opposite for research; there is a need for bettering the informed consent process to protect the poor and vulnerable. For now, when the time comes for the courts to deal with cases arising out of lack of informed consent in research in India, they will first look at the law of informed consent within the treatment context to draw parallels with the research context, and here they would find an

66. The *Bolam* test has been derided in its support for medical paternalism in almost all scholarly works pertaining to the evolution of the law of informed consent. See K. McCombe, ‘Paternalism and Consent: Has the Law Finally Caught up with the Profession?’, *Anaesthesia* 70 (2015), pp. 1016–1019; H. Teff, *Reasonable Care: Legal Perspectives on the Doctor–patient Relationship* (Oxford: Oxford University Press, 1995).

67. *Kohli* at [26].

obiter dictum that called informed consent ‘meaningless’ and ‘irrelevant’ for poor patients.

On the matter of informed consent from the perspective of the ‘takers of consent’, the judges in *Kohli* opined:

The position of doctors in government and charitable hospitals, who treat them, is also unenviable. They are overworked, understaffed, with little or no diagnostic or surgical facilities and limited choice of medicines and treatment procedures. They have to improvise with virtual non-existent facilities and limited dubious medicines. They are required to be committed, service oriented and non-commercial in outlook. *What choice of treatment can these doctors give to the poor patients? What informed consent can they take from them?*⁶⁸ (My emphasis)

Although the premise of this paragraph is sympathetic, the Court’s observations lead to unsound implications. If this rhetorical observation by the court were to be advanced further, it would mean that the lack of resources available to a doctor would absolve the doctor from the duty to take informed consent from her patients. If this reasoning were to be extended to the research context, it would mean absolving researchers from their duty to take informed consent because of time constraints, funding problems, lack of administrative support and so on. This, however, is neither the established legal position nor the ethical one. Fortunately, these observations were made as obiter dicta, subsequent to which the court chose *Bolam* over *Canterbury* citing the ‘ground realities’ in India. It said:

We have, however, consciously preferred the ‘real consent’ concept evolved in *Bolam* . . . in preference to the ‘reasonably prudent patient test’ in *Canterbury*, *having regard to the ground realities in medical and health-care in India*. But if *medical practitioners and private hospitals* become more and more commercialized, and if there is a corresponding increase in the awareness of patient’s rights among the public, inevitably, a day may come when we may have to move towards *Canterbury*. But not for the present.⁶⁹ (My emphasis)

This reasoning is equally questionable. This implies that for the court to have considered an autonomy-enhancing standard of information disclosure, there would need to be some evidence that Indian citizens were more aware of their rights as patients.⁷⁰ The ‘ground realities’ of India observed by the court show that there is an asymmetrical power relationship between a doctor and a patient. The court either misconstrues these ground realities or misconstrues the *Bolam* test. For *Bolam* enhances this asymmetry, particularly if there is a poor, or possibly not highly educated or unaware, patient being

68. Op. cit. at [27].

69. Op. cit. at [33].

70. This might also lead to the implication that poor and unaware patients do not require a stronger protection of their right to autonomy and informed consent unless commercialisation of medicine become commonplace. However, this might be an uncharitable interpretation of the quote.

treated by a highly educated and well-regarded doctor with expert colleagues in tow. *Bolam* makes it easier to disregard the rights of poorer patients.

If we look at the research context in India, we will find that most privately sponsored clinical research is commercial by nature and not all participants are aware of their rights.⁷¹ Nevertheless, the difference between research and treatment is such that the unaware participants need to be given more information related to the study by the researcher. The *Bolam* test in affirming that the ‘doctor knows best’ is quite redundant for the research context as it goes both against the ethical guidelines and informed consent process required by the statute that governs clinical research in India.⁷² Albeit that the researcher/investigator of a study might ‘know best’ in terms of what the likely risks are, he or she is nonetheless required to disclose all relevant information about the study to the participant. Such disclosure cannot be measured against what other professionals in the field do considering that every research study is different. Furthermore, in most studies, some of the risks are unknown; in fact, most studies are conducted on human subjects to uncover risks involved in experimental procedures or drugs. Therefore, the potential risks that are generally disclosed in a similar study of a similar drug might be completely different from potential risks involved in the study of another. As such, and by the farthest stretch, if the courts were to consider the *Bolam* test as applicable to the research context, they could look at the ICMR or GCP ethical guidelines as the professionally accepted standards in human subject research. Given that most guidelines are released by professional bodies headed by people from a given profession, they can safely be regarded as the codified norms that ought to govern the behaviour of those professionals. This is perhaps the only approach that could somehow accommodate the *Bolam* test within the research context.

Let us now look at another reason given by the court in the *Kohli* case to prefer the *Bolam* test to the *Canterbury* principle. The court noted:

People in India still have great regard and respect for Doctors . . . There is an atmosphere of trust and implicit faith in the advice given by the Doctor. The Indian psyche rarely questions or challenges the medical advice. Having regard to the conditions obtaining in India, as also the settled and recognized practices of medical fraternity in India, we are of the view that to nurture the doctor-patient relationship on the basis of trust, the extent and nature of information required to be given by doctors should continue to be governed by the *Bolam* test rather than the ‘reasonably prudent patient’ test evolved in *Canterbury*. It is for the doctor

71. See V.D. Joshi et al., ‘Public Awareness and Perception of Clinical Trials: Quantitative Study in Pune’, *Perspectives in Clinical Research* 4 (2013), pp. 169–174; Nadimpally and Bhagianadh, “‘The Invisible’”.

72. The statute that governs clinical research in India is the Drugs and Cosmetics Act (DCA) 1940. It lays down the informed consent procedure in Schedule Y of the Drugs and Cosmetics Rules 1945, which is appended to the DCA. s. 3(ii) of Schedule Y clearly states that the ‘[i]nvestigator [of a research study] shall provide information to the clinical trial subject through informed consent process as provided in Appendix V about the essential elements of the clinical trial and the subject’s right to claim compensation in case of trial related injury or death’ (my emphasis).

to decide, with reference to the condition of the patient, nature of illness, and the prevailing established practices, how much information regarding risks and consequences should be given to the patients, and how they should be counched, having the best interests of the patient.⁷³

All the justifications given by ethical theorists to strengthen informed consent by increasing dialogue between doctor–patient/researcher–research subjects, such as protection of patients/subjects and restoration of trust, were taken by the judges in this judgment and formulated into reasons for supporting the paternalistic *Bolam* test. The court reinforced the paternalism, which has now been rejected by most common law jurisdictions, in stating that for the Indian patient, a doctor should make decisions as other doctors see fit. One cannot help but note that not one sound legal reason was given by the Supreme Court for rejecting the pro-patient *Canterbury* principle. Perchance the judges should have taken note of the comments made by Shepherd et al., regarding legal justice in favour of patient rights; they wrote:

Law, especially in the realm of litigation, involves questions of justice. It can be no more pro-patient than it can be pro-plaintiff or pro-defendant. But if we return to the idea of patients generally – rather than the specific patient – being benefited or at least not harmed by a particular ruling, or to the idea of law that supports healing relationships, then an explicit normative stance in favour of patients does not seem quite so out of keeping with more general notions of legal justice.⁷⁴

A final aspect of the *Kohli* case worthy of note is that the court used this case as an opportunity to clarify its position on medical negligence and the test for information disclosure, but it imposed liability on the respondent under the tort of battery. Referring to some established precedents regarding the tort of battery,⁷⁵ the judges in the *Kohli* case held that:

73. *Kohli* at [31].

74. L. Shepherd and M.A. Hall, 'Patient-Centered Health Law and Ethics', *Wake Forest Law Review*, 45 (2010), p. 1450; while also citing J.H. Krause, 'Can Health Law Truly Become Patient-Centered?', *Wake Forest Law Review* 45 (2010), pp. 1490–1492.

75. The court referred to the *Canterbury* case, and also to the book, A. Grubb, *Principles of Medical Law*. 2nd ed. (Oxford; Oxford University Press, 2010), ¶ 3.04, p. 133, which explained that '[a]ny intentional touching of a person is unlawful and amounts to the tort of battery unless it is justified by consent or other lawful authority'. The judges cite *Murray v. McMurchy*, 1949 (2) DLR 442, BC, where the Supreme Court of British Columbia in Canada, was looking at a claim under battery. In this case, during the course of a patient undergoing C-section, the doctor found fibroid tumours in the patient's uterus. Concluding that such tumours would be a danger in case of a future pregnancy, the doctor performed a sterilisation operation. The court upheld the claim for damages for battery and held that sterilisation could not be justified under the principle of necessity, as there was no immediate threat or danger to the patient's health or life, and there was only consent for C-section not for sterilisation.

Consent given only for a diagnostic procedure, cannot be considered as consent for therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other treatment procedure.⁷⁶

Thus, the court in the *Kohli* case held that the lack of consent for hysterectomy and SPO was ‘an unauthorized invasion and interference with appellant’s body’, thereby holding the respondent liable under the tort of battery.

The *Kohli* case is the current precedent on the law of informed consent in India; so far, it has not been challenged.⁷⁷ Briefly, the court held that a reasonable practitioner should decide what a patient must know regarding her treatment rather than the patient herself because Indian patients are poor and deeply trust their doctors. Therefore, to nurture the trust between the poor Indian patient, who is lucky enough to get any treatment, and the doctor, who is overworked, the *Bolam* test was more suited to the Indian reality.

The *Kohli* case demonstrates India’s legal position on informed consent cases in the treatment context, but it is unclear whether individuals have a private right to action to receive damages for lack of informed consent in clinical research in India. So far, there has not been a single reported case utilising that cause of action.⁷⁸ This maybe because as commentators have suggested, there is not much tort litigation in India due to the high costs of court action.⁷⁹ It is true that tort law development has been somewhat patchy in India.⁸⁰ Even though there is a significant body of case law on medical negligence,⁸¹ most of it derives from foreign precedents and there is, to the author’s knowledge, no precedent on lack of informed consent in clinical research as the sole cause of action. Therefore, if someone wanted to employ a private law remedy under tort law in India for lack of informed consent in clinical research, the courts would be likely to refer to how the private right to action is invoked in other common law jurisdictions. Let us first find

76. *Kohli* at [32].

77. Most recently, this case was used as the standard for medical negligence cases arriving before the National Consumer Disputes Redressal Commission (NCDRC) in *Vinhans Hospital and Ors. v. Anand Kumar Jha and Ors.* (2015).

78. This conclusion is based on my research conducted on online legal databases and legal resources in the legal libraries in India.

79. See K.B. Agrawal and V. Singh, *Private International Law in India* (The Hague: Kluwer Law International, 2010), p. 135.

80. P. Reddy, ‘A Small but Significant Victory for Tort Law and Civil Liberties’, *Live Law* 6 October 2017. Available at: <http://www.livelaw.in/small-significant-victory-tort-law-civil-liberties/> (accessed 2 February 2020). In this article, the author while writing a commentary on a rare case specifies why tort law in India has not been fully developed in form and function says ‘In India due the enactment of sector specific legislation we have a splintered system of special fora like the consumer courts or the railways claims tribunal or the motor vehicle claims tribunal that deal with claims that would otherwise be dealt with by civil courts under ordinary tort law’ and he also raises concerns with the Constitutionalisation of private wrongs and admits how rare it is for people to approach civil courts when their civil rights are infringed by another person or by the government.

81. See T.K. Koley, *Medical Negligence and the Law in India: Duties, Responsibilities, Rights* (Oxford; Oxford University Press, 2010).

out if such a private right to action for lack of informed consent is recognised in other common law jurisdictions.

Informed consent to research in the United States and Canada

There has been a steady increase in lawsuits in the United States based on investigators' failure to obtain informed consent.⁸² Despite such an increase in lawsuits, scholars claim that the courts have rarely succeeded in extending a right of private action to lack of informed consent in clinical research.⁸³ An analysis of case law from the United States confirms this claim. For instance, in *Wright v. Fred Hutchinson Cancer Research Center*,⁸⁴ the Cancer Research Center and its investigators were sued by family members of cancer patients who had participated in a series of clinical trials which led to several deaths. The US District Court for the Western District of Washington granted the Center's motion for judgment in its favour, the jury finding that the trial participants had given their consent.⁸⁵ The court held that the breach of informed consent in clinical trials is not deemed a violation of a federal right as defined by law. It also held that there was no statutory basis for a private right of action that the petitioners sought to assert given that alternate tort or procedural remedies were available to the petitioners.

If the *Wright* case was to be applied in India, the court could find a similarity in the statutory absence of a right to private action. The Drugs and Cosmetics Act does not prescribe any remedial clause for the failure to observe informed consent procedures for clinical trials. Moreover, a potential claim for lack of informed consent leading to violation of a fundamental right guaranteed by the Constitution of India would not stand if an Indian court was to consider what the US court in *Wright* noted:

... [the] defendants' failure to make disclosures necessary to the informed consent process in a therapeutic, experimental setting, does not implicate rights that are so rooted in the tradition and conscience of our people as to be ranked as fundamental. A doctor's tortious failure to obtain informed consent is not a threat to our citizens' enjoyment of ordered liberty, even when the doctor is employed by the state.⁸⁶

However, there have been cases where courts in the United States have held that research participants can bring a tort claim for lack of informed consent in the research

82. M.M. Mello et al., 'The Rise of Litigation in Human Subjects Research', *Annals of Internal Medicine* 139 (2003), p. 40; A. Dembner, 'Lawsuits Target Medical Research-Patient Safeguards, Oversight Key Issues', *Boston Globe* 12 August 2002. Available at: <https://www.sskrplaw.com/lawsuits-target-medical-research-patient-safeguards-oversight-ke.html> (accessed 2 February 2020).

83. V.G. Koch, 'Private Right of Action'.

84. *Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286 (W.D. Wash. 2002).

85. After due consideration of facts, the jury found that the plaintiffs did not prove any missing information that would have changed the patients' decision, *Wright* [1297].

86. *Wright* [1296].

context. But these cases have either involved particularly vulnerable population groups or investigators failing to disclose information about foreseeable risks in their research.

In an example of litigation concerning vulnerable populations, *Grimes v. Kennedy Krieger Institute*⁸⁷ involved non-therapeutic health research on children. Researchers from Kennedy Krieger Institute (KKI) conducted a 2-year study to measure and compare lead dust levels collected in housing with lead levels in blood samples drawn from children living in those homes. In this case, the trial court ruled in favour of the researchers, but the Maryland Court of Appeals reversed the decision. The Court of Appeals held that the informed consent requirement under the Common Rule⁸⁸ created a duty of care that arose out of a 'special relationship'⁸⁹ between the investigator and research participant and a breach of such duty was actionable under state law.

This case was unusual in finding a duty where the research did not seem to have introduced participants to additional risks (they were already living in the premises before the study). The duty was seemingly based on a 'failure to warn' when the risk was not introduced by the research itself.⁹⁰ The court reiterated the *Canterbury* principle and held that the study conducted by KKI lacked the fully informed consent of participants and the research did not comply with federal regulations.

It is important that we analyse this case further to determine whether it extends a private right to action in *all* research-based cases. The court determined that a 'special relationship' existed in this case because it involved healthy children who required surrogate consent to participate in the study. Moreover, the research was non-therapeutic (gave no direct benefit to the research participant) and there was more than 'minor' risk involved. These factors made the case 'special'. Furthermore, the court said, 'whether a duty of care existed between the parties is a question to be determined by the trier of fact on a case-by-case basis'.⁹¹ Koch suggests, and I concur, that since no other court in the United States has found such a 'special relationship' between investigators and research participants, 'it would be presumptuous to assume, based on this single court's narrow holding, a general private right of action for participants for failure to disclose the risks and benefits of a research protocol'.⁹² I would argue that if such a case were to come before a court in India, it ought to follow a similar 'case-by-case' strategy

87. *Grimes v. Kennedy Krieger Institute Inc*, 366 Md 29, 782 A2d 807 (2001).

88. 45 C.F.R. §46 et seq. (2002). The Federal Policy on the Protection of Human Subjects in the United States, also called the 'Common Rule', was adopted by federal government agencies to promote uniformity in the conduct of human subject research.

89. The court said 'Such research programs normally create special relationships and/or can be of a contractual nature, that create duties. The breaches of such duties may ultimately result in viable negligence actions', *Grimes* at [834].

90. *Op. cit.* The decision rested on the fact that the Kennedy Krieger Institute waited 9 months to disclose 'hot spots' of high lead exposure to parents, even after the child's blood was found to contain elevated levels of lead.

91. *Grimes* at [858]. The court in *Grimes* also referred to *Williams v. Maynard*, 359 Md. 379, 754 A.2d 379 (2000) where the majority opinion concluded the same.

92. Koch, 'A Private Right of Action for Informed Consent in Research', p. 193.

to determine the nature of relationship between the research participant and the researcher.

Also notable in the US jurisprudence are cases confirming a heightened duty of disclosure in cases of research as opposed to treatment. In *Whitlock v. Duke University*,⁹³ the plaintiff suffered permanent organic brain damage during a simulated deep dive experiment. He claimed that the University was negligent in its duty to fully inform the participant about the foreseeable risks. The court held that the degree of required disclosure of risks is higher in the non-therapeutic research context than in the treatment context.

If a case based on a similar cause of action were to arrive before a court in India, the court should reconsider its standard for disclosure of information.⁹⁴ As noted earlier, the *Bolam* test does not do justice to the relationship between a research subject and an investigator or researcher. The nature of scientific research into new entities is such that few investigators would be able to comment on the foreseeable risks involved in another investigator's research. If the risks are unknown, as they often are in research, then research subjects need to be explicitly warned about this. This negates the need for expert opinion of other investigators on foreseeable risks. *Bolam*, in relation to information disclosure, has largely been abandoned in other common law jurisdictions. If a court in India were to use a pre-existing standard for information disclosure from the treatment context for dealing with a case under the research context, it ought to choose between *Canterbury* or *Montgomery*. Then, at least, the standard of disclosure would be determined by the yardstick of what a reasonable person in the participant's position ought to have known about the experimental procedure.⁹⁵

Also requiring a nominally higher degree of disclosure for research rather than the treatment context, the Canadian Court of Appeal in Saskatchewan in *Halushka v. University of Saskatchewan et al.*⁹⁶ was of the opinion that the duty of researchers to participants 'is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient'.⁹⁷ *Halushka* involved a student who participated in a test of a new anaesthetic. He signed a consent form and was informed that the test involving the new drug was safe. During the test, the plaintiff suffered from a cardiac arrest but was resuscitated. The plaintiff sued the defendants for trespass to person and negligence. The plaintiff's claim for both trespass and negligence succeeded at the original trial. He was allowed to recover damages from the defendants, and the Court of Appeal upheld the verdict for damages but only under trespass, not negligence. While

93. *Whitlock v. Duke University*, 637 F. Supp. 1463 (M.D.N.C. 1986).

94. *Kohli*.

95. But commentators like Haavi Morreim suggest that none of the legal standards, including the reasonable person and objective standard, for information disclosure seem apt for the research context. He is of the opinion that the research context requires a sharply different approach. See E.H. Morreim, 'Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities', *Journal of Law and Medical Ethics* 32 (2004), p. 479; The Belmont Report, 1979.

96. *Halushka v. University of Saskatchewan et al*, 53 D.L.R. (2d) 436 (Sask. C.A.) (1965).

97. *Halushka* at [29].

reaching its decision, the court seemed to have construed the non-disclosure as so substantial and misleading that the student had in effect given no consent. The court noted that in medical cases, an actionable trespass to person is said to have occurred if consent is not informed and freely given. The court also went into the risk versus benefit analysis of the research. It held that since the plaintiff was simply a research subject who received no therapeutic benefit from the research, he was entitled to a complete and frank disclosure of all facts, probabilities and opinions, which a reasonable person might be expected to consider before consenting to the test.⁹⁸

Halushka considered the differences between the research and treatment context and suggested that the standard of information disclosure under informed consent was a little higher than that required for in treatment. This was because there could be no case for exception to omit information for the welfare of the research participant, like a doctor could for the benefit of the patient. Morreim, while writing about the legal treatment of informed consent in research, has written about the need for courts to understand the difference between the two contexts. He clarifies that ‘research injuries are [not] somehow worse (or better) than medical malpractice, or that we need to augment (or diminish) the available causes of action against research errors’.⁹⁹ He thinks, and I agree, that courts need to be erudite and clear about research being a different context than treatment, particularly if they are to build a satisfactory foundation by which to guide conduct in research.

Halushka also attempted to make a distinction between the tort of battery and negligence quite unlike the Indian court in *Kohli*. It appears that the court in *Kohli* was open to the idea of determining a liability under either negligence or battery, whichever suited the facts of the case more.¹⁰⁰ However, *Halushka* was not entirely sharp on this distinction as it is not clear how grave the non-disclosure would need to be for there to be no effectual consent.

The choice between torts of battery and negligence can be blurry in some cases of inadequate consent as it largely depends on the degree of non-disclosure of information. However, it is clear that battery is the appropriate tort for non-consensual cases of research. A leading precedent for non-consensual clinical research is *Mink et al. v. University of Chicago*¹⁰¹ where the plaintiff along with a thousand other women was given diethylstilbestrol (DES) as part of a double-blind study to study its effect on preventing miscarriages. The plaintiffs were neither told that they were to be a part of an experiment nor were they told that they were being given DES, as such they alleged that the drug caused their newly born daughters to develop cervical abnormalities and that it led to an increased risk of cancer in them and their daughters. The court held that the cause of action that could succeed was battery since there was a complete lack of

98. Op. cit.

99. Morreim, ‘Litigation in Clinical Research’, p. 476.

100. The court in the *Kohli* case responded to a question framed as: ‘Whether the Respondent is guilty of the tortious act of negligence/battery amounting to deficiency in service, and consequently liable to pay damages to the appellant?’, *Kohli* at [37].

101. *Mink v. University of Chicago*, 460 F.Supp. 713 (1978).

consent. Here again, as in *Halushka*, the court differentiated between the torts of battery and negligence holding that ‘where the patient has not consented to the treatment, it is meaningless to ask whether the doctor should have revealed certain risks necessary to make the consent an “informed” one’.¹⁰²

Taking stock of the position on lack of informed consent in research, the US courts have recognised a ‘special relationship’ between investigators and research subjects in a case involving children, even where the researchers had not introduced the risks the children were exposed to, and they have recognised that a higher degree of disclosure is needed in research cases. They have also held that lack of informed consent does not provide a private right of action under federal regulations (Common Rule) and if an alternative remedy exists (as it does in tort); lack of informed consent is not a violation of due process (violation of life and person liberty in India).¹⁰³ The Canadian position is that a higher degree of disclosure is needed for research, especially for non-therapeutic research in which the risk is higher and which is of little benefit to the research subject. It is pertinent to note that each of these cases had different facts and completely different claims, which shows that the right to recover for lack of informed consent in research is not as established as it is under treatment.

All these cases show that a court in India would have the option to entertain a claim arising out of lack of informed consent in research under the torts of battery or negligence (depending on the facts of the case). As for a private right to action for lack of informed consent in research, whether arising from a statute or other regulatory provision in India, the court would have a difficult time finding one. If a claim under lack of informed consent is filed in the higher courts as a violation of a fundamental right, it will remain at the discretion of the court to determine whether the lack of informed consent amounted to a violation of the right to life and/or personal liberty (a position rejected by the US court in *Wright*).

Having outlined the position of the Indian courts on informed consent and suggested the lessons that could be learned from some legal cases from United States and Canada, I acknowledge that simply focusing on law in this area is unlikely to solve the problems with the *actual process* of informed consent.¹⁰⁴ But the development of a clear and concise legal remedy is required to tackle grievances arising out of a lack of informed consent in research. Nevertheless, there are some limitations that need to be accounted for in any discussion on legal remedies. The next section will draw out some of these limitations.

102. *Mink* at [716].

103. The Constitution of India, 1950, Article 21. This is the Indian equivalent of the due process clause in the United States.

104. As informed consent in research is a *continuous* process (lasting the duration of the many years involved in a trial) which is guided better through ethics than by law. Empirical researchers have found numerous problems with the *process* of consent in research concerning exploitation, comprehension, undue influence, coercion, legibility of consent document and so on. These issues are not covered by the post-fact, remedy-oriented, legal understanding of informed consent that is tackled in this article.

Some limitations

In the remaining sections, I will address one general and two context-specific limitations pertaining to development of a legal doctrine for a lack of informed consent in research in India.

Limits of tort law in general

It is generally accepted that the legally recognised right to give a consent which is informed is aimed at protecting the autonomy of the research participant. But commentators question the sufficiency of the present legal doctrine with regards to protection of autonomy. Morreim, for example, is of the opinion that the standard legal doctrine of informed consent does not sufficiently protect autonomy where there is no demonstrable physical harm to the individual:

[B]ecause standard informed consent doctrine usually limits recovery to cases featuring a physical or other separate injury, it can fail to honor human autonomy in cases where someone's right to choose has been abused without demonstrable physical damage. If this is a problem in ordinary medicine, it is even more so in the research setting.¹⁰⁵

I do not think that this criticism is sound to the extent that there are claims that can succeed under the tort of battery without a demonstrable physical damage.¹⁰⁶ Moreover, even though it is rare and often difficult to claim, people with no physical injury after having proven 'infliction of emotional distress' have also been able to recover damages under tort law.¹⁰⁷ Serious dignitary harms¹⁰⁸ can also be rectified under constitutional rights. Yet some commentators have demanded a new dignitary tort for lack of informed consent in research.¹⁰⁹

105. Morreim, 'Litigation in Clinical Research'.

106. See A. Best et al., *Basic Tort Law: Case, Statutes and Problems*. 4th ed. (New York: Wolters Kluwer, 2014).

107. Lack of informed consent in research could potentially lead to emotional distress. Intentional Infliction of Emotional Distress tort is an example of the strength of tort law as it shows flexibility to accommodate other forms of 'harm'. For an analysis of the development of tort law in the area of 'emotional distress', see J.L. Kircher, 'The Four Faces of Tort Law: Liability for Emotional Harm', *Marquette Law Review* 90 (2007), pp. 789–920.

108. Dignitary harms are harms that have been 'caused by conduct that overrides patients' autonomy, treats them as less than human, and denigrates them as human beings'. See D.S. Davis, 'The Ambiguous Effects of Tort Law on Bioethics: The Case of Doctor-Patient Communications', *Clinical Ethics* 21 (2010), p. 265, such a dignitary harm will most certainly be redressable under the Constitution of India under Article 21, which provides for protection of life and liberty. The degree of erosion of autonomy matters and 'treatment of a human as less than human' is a higher degree of violation of autonomy. A right to live a life with dignity has been endorsed by the Indian Supreme Court in the case *Francis Coralie Mullin v. Administrator, Union Territory of Delhi and others* (1981) 1 SCC 608.

109. A. Meisel, 'A Dignitary Tort' as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent, *Journal of Law, Medicine and Ethics* 16 (1988), pp. 210–218; A. Weisbard, 'Informed Consent: The Law's Uneasy Compromise with Ethical Theory',

While the right to recover damages for lack of informed consent in research is not as established as the right to recover under treatment, and there is a need for clarity in law pertaining to the treatment of lack of informed consent in research, there is arguably enough flexibility under tort law to address the different nature of the investigator–subject relationships.¹¹⁰ An example of this sort of flexibility is the *Grimes* case, in which the court acknowledged the wide knowledge gap between investigators and research subjects and found a ‘misalignment of interests’.¹¹¹

Limitations of the law of informed consent in India

In addition to the options mentioned in the third section, there is another, albeit indirect, route that an Indian court might prefer to use to determine claims arising from a lack of informed consent in research, especially considering that more than 10 years have elapsed since *Kohli*. In the second section, it was noted that the UK, through *Montgomery*, has moved away from *Bolam* towards a more patient-centred standard of information disclosure. The Indian Supreme Court could, therefore, reject *Bolam* test in favour of *Montgomery* (despite rejecting *Canterbury* in 2008) in the future medical negligence or battery cases and then extend *Montgomery* to health research cases. Although this move would have some advantages, the next section will explain why it seems not entirely fitting (legally, ethically and practically) for the research context.

Why not Montgomery?

At first sight *Montgomery* may be perceived as a step forward in dealing with negligence cases based on failure to adequately inform a research participant. Scholars usually agree that *Montgomery* is more patient-centred than its predecessor *Bolam* and that it depicts a steady move towards informed consent becoming a more personalised process in not just treatment but also in research.¹¹² It is well established that the informed consent process in clinical trials, from counselling sessions until the end of research, requires a continuous dialogue between researchers and participants. *Montgomery* recognises that a ‘doctor’s advisory role involves dialogue’¹¹³ and if extended to research, information to

Nebraska Law Review 65 (1986), p. 763; E.H. Morreim, ‘In Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve’, *Houston Journal of Health Law and Policy* 4 (2003), pp. 1–86.

110. As a side note, such relationship does not have to be a medical negligence claim. It could be covered under general professional negligence. If a duty of care can be established in such a relationship as per the Caparo test laid out by the UK House of Lords following the case *Caparo Industries PLC v. Dickman* [1990] UKHL 2, then liability could be imposed on investigators and perhaps even on research sponsors.
111. S.A. Alessi, ‘The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?’ *Hastings Law Journal* 64 (2013), p. 1715; *Grimes*.
112. J.V. McHale, ‘Innovation, Informed Consent, Health Research and the Supreme Court: *Montgomery v Lanarkshire* – A Brave New World?’ *Health Economics, Policy and Law* 12 (2017), pp. 435–452.
113. *Montgomery* at [90].

participants would need to be in the form of a dialogue with participants themselves determining what information they would want to be provided for the research.

However, *Montgomery* is not devoid of criticism from scholars and medical practitioners alike.¹¹⁴ One main problem concerns the standard for the assessment of disclosure of material risks which, according to the court, ought to be 'fact-sensitive, and sensitive also to the characteristics of the patient'.¹¹⁵ This is close to making the standard of information disclosure subjective to an individual patient's/participant's need for information. Although autonomy-enhancing, the subjectivity standard risks cases where research participants refuse full information. As noted earlier, research involves uncertainty in risks, and it is these risks that might cause harm to a participant. Given that all guidelines in human subject research require complete disclosure about known and unknown risks in a study, *Montgomery* appears to be partly untenable for the research context.¹¹⁶ Furthermore, *Montgomery* supports therapeutic privilege to an extent, holding that a doctor is 'entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health'. This does not translate well into the research context for any research-related information, no matter how detrimental to the participant's health, cannot be withheld from a participant without ethically and legally invalidating the participant's consent to research.

Nonetheless, if extension of case law from treatment is the *only* option to deal with lack of informed consent in research, then despite its problems, *Montgomery* is better suited to research than *Bolam* in as much as it supports a dialogue-based patient-centred standard of information disclosure rather than a paternalistic one. Therefore, Indian courts have the option of rejecting *Bolam* in favour of *Montgomery* in forthcoming negligence cases and partly applying its ratio to lack of informed consent in research. For the near future, however, this option seems unlikely for three reasons: First, the Indian court in *Kohli* gave widespread poverty and trust in doctors as reasons to reject *Canterbury's* patient-centred test and to retain *Bolam*. These conditions still persist and could be argued to apply equally to the adoption of *Montgomery*. Second, the reasoning in *Kohli* and *Bolam* has been reiterated in several recent cases which suggests that despite being aware of the existence of *Montgomery*, Indian courts are comfortable with the status quo.¹¹⁷ Third, I have hinted earlier that tort litigation in India is sparse and negligence

114. For extensive commentary, see R. Heywood, 'R.I.P. *Sidaway*: Patient-Oriented Disclosure-A Standard Worth Waiting for?: *Montgomery v Lanarkshire Health Board* [2015] UKSC 11', *Medical Law Review* 23 (2015), pp. 455-466; A.M. Farrell and M. Brazier, 'Not so New Directions in the Law of Consent? Examining *Montgomery v Lanarkshire Health Board*', *Journal of Medical Ethics* 42 (2016), 85-88; J. Montgomery and E. Montgomery, 'Montgomery on Informed Consent: An Inexpert Decision?' *Journal of Medical Ethics* 42 (2016), pp. 89-94.

115. Op. cit. at [89].

116. McHale, 'Innovation, Informed Consent, Health Research'.

117. *Montgomery* has been alluded to in some new cases on informed consent, but only in passing; *Kohli* being the leading precedent has to be followed. *Bolam* continues to be the norm. See *Manmohan Kaur v. M/S. Fortis Hospital & 2 Ors*, National Consumer Disputes

cases are predominantly being dealt with under the Consumer Protection Act as ‘deficiency in service’.¹¹⁸ Therefore, it might be some time before the Supreme Court has the opportunity to lay down a new leading precedent on informed consent in India. This also ties up with the general status of tort law in India as will be discussed next.

Tort law in India

Tort law development has been stunted in India. On problems facing the law of torts in India, Thanvi writes:

The received English law, and more especially law of torts, has not fared well with the Indian conditions of life, and as such it has not been able to sent [*sic*] its roots deep into the recesses of the Indian soil.¹¹⁹

There is little reliable data to suggest how much tort litigation has occurred as cases in trial courts generally go unreported. Even in the higher courts, only those cases that are marked ‘fit for reporting’ by the judges in the High Courts and the Supreme Court are published.¹²⁰ But from a cursory glance at reported cases, it is evident that litigation under tort law is sparse when compared to other common law jurisdictions. Marc Galanter conducted a 10-year survey (1975–1984) on tort litigation in India and concluded that tort law in India was unsystematic, largely neglected and infrequently resorted to by the people.¹²¹ Noting the poor development of tort law in India, Cassels also remarked that, ‘[a]t least until now the law of tort in India is little more than a myth about how people would be cared for in a better world’.¹²² While the works cited rely on data from decades ago, little seems to have changed to undermine their findings.¹²³ These works were some of the few exhaustive academic commentaries on the status of tort law in India, suggesting, in addition, that not much academic attention has been paid to it.

Nevertheless, a significant portion of the criticism directed against tort law in India is procedural and logistical. There is a long-standing problem of paucity of judges in

Redressal Commission (NCDRC), 29 June 2018; Mrs. Surjeet Sodhi & Ors vs Fortis Hospital & Anr, NCDRC, 20 January, 2020.

118. Op. cit.

119. S.C. Thanvi, ‘Law of Torts’, in J. Minattur, ed., *The Indian Legal System*. 2nd ed. (New Delhi: Indian Law Institute, 2006), pp. 668–671.

120. Generally, it is only the cases that appear before High Courts, Supreme Courts, Labour Tribunal, Company Law Appellate Tribunal, Consumer Disputes Redressal Fora and some other judicial and quasi-judicial bodies that get reported, but not tort cases that appear before lower courts. See S.K. Bhatia, ‘Specific Problems of Torts Law in India’, *Journal of the Indian Law Institute* 11 (1969), pp. 510–519.

121. M. Galanter, ‘When Legal Worlds Collide: Reflections on Bhopal, the Good Lawyer, and the American Law School’, *Journal of Legal Education* 36 (1986), pp. 292–310, 296.

122. J. Cassels, *The Uncertain Promise of Law: Lessons from Bhopal* (Toronto: University of Toronto Press, 1996), p. 153.

123. P. Reddy, *Live Law* 6 October 2017.

India,¹²⁴ but more importantly, there is a lack of specialisation among lawyers. As Galanter, based on his years of research conducted on tort law in India, noted '[o]ne may visualize Indian lawyers as stuck in a hyper-individualized bazaar economy in which virtually all lawyers offer the same narrow range of services'.¹²⁵ This remark was made three decades ago, but even today, with the advent of many professional and large scale law firms, tort law as a specialisation has not seen much development. Considering that Indian lawyers work with little to no institutional support for specialised knowledge, with no specialist organisation or specialised technical publication in tort law and coupled with the recent trend of constitutionalising private law,¹²⁶ Galanter's critique from 1986, that tort law in India is unsystematic and largely neglected, still holds. There are also significant barriers to access, such as a lack of legal aid, high court fee and lack of insurance to cover legal fees. These barriers, along with the protracted delays and meagre recoveries, have made people wary of litigation in India.

Despite all these drawbacks, it is nonetheless possible that the courts in India might adopt an innovative application of tort law¹²⁷ if presented with the right opportunity. As Basu fittingly notes:

It seems that the problems of tort law in India lie not so much in the laws themselves as in their use and application. As such they may have much to do with economic and political realities of a more general "underdevelopment" in a Third World nation. After all the number of judges and courts available is really a product of economic necessities and political choices.¹²⁸

Logistical problems aside, there is reason to believe that the Indian courts will forego their current approach to informed consent under tort law and adopt a modern approach to cases dealing with lack of informed consent. The source of this optimism lies in a recent statement pronounced by a two-judge bench of the Supreme Court that said '[i]n the times to come, litigation may be based on the theory of lack of informed consent'.¹²⁹

124. See A. Mathur, 'State on Indian Judiciary Report: 'Lack of Judges, Inefficient Management Behind Delays'', *The Indian Express* 11 August 2016. Available at: <http://indianexpress.com/article/india/india-news-india/judges-shortage-pending-cases-inefficient-management-2967172/> (accessed 2 February 2020).

125. Galanter, 'When Legal Worlds Collide', p. 297.

126. Balganes, 'The Constitutionalization of Indian Private Law'.

127. Much like their innovation and legal creativity in galvanising law for the poor, see J. Cassels, 'Judicial Activism and Public Interest Litigation in India', *American Journal of Comparative Law* 37 (1989), pp. 495–519.

128. A. Basu, 'Torts in India: Dharmic Resignation, Colonial Subjugation, or "Underdevelopment"?' *The South Atlantic Quarterly* 100 (2001), pp. 1053–1070, 1068.

129. *Malay Kumar Ganguly v. Sukumar Mukherjee & Ors*, (2009) 9 SCC 21, the Court observed (without referring to *Kohli*) that with changing times the '[d]octors increasingly must engage with patients during treatments especially when the line of treatment is a contested one and hazards are involved. Standard of care in such cases will involve the duty to disclose to patients about the risks of serious side effects or about alternative treatments'.

Conclusion

With a booming clinical research industry and large swathes of vulnerable population groups, India needs to move abreast with the legal developments in informed consent in other common law jurisdictions. It is true that *individual* cases claiming a lack of informed consent in research do not often reach a court of law, and in India's case, they have not reached the court at all, but this is mostly because there is a legal lacuna that needs to be filled. For now, the *Bolam* test that the Indian courts have preferred in the treatment context would be inept to deal with the 'special relationship' between a researcher and a research subject. Moving forward, courts also need to be erudite about research being a different context than treatment, particularly if they are to build a suitable foundation by which to guide conduct in research.

The legal doctrine of informed consent focuses on the post-fact and post-injury aspect of informed consent, which some might consider trivial given the ethical problems faced by researchers *during* the informed consent process. But it would be naive to deny the significant effect that law has on the whole process of informed consent. People give and take consent in the shadow of law. For that, the development of clear and concise legal standards is required to tackle grievances arising out of a lack of informed consent in research.

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