

Policy Report

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**Bridging Multiple Gaps:
Strengthening India's Research Protocols for Assistive Aids**

Swapna Sundar



THE HINDU CENTRE

for

Politics and Public Policy

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Strengthening India's Research Protocols for Assistive Aids**

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ABSTRACT

India is home to 2.68 crore persons with disabilities comprising 2.21 per cent of its population (2011 Census). However, less than 16 per cent of persons with disabilities have any assistive aids and appliances. In general, Indian innovators in assistive device technology lack crucial understanding of the market realities and possess a sketchy understanding of issues that have important implications for the disability sector. This has resulted in poor research and engineering of assistive devices, directly affecting the quality of support given to the disabled.

Some of the issues that have not been fully understood by Indian innovators are: ‘freedom-to-operate’ and consequent infringement of Intellectual Property Rights (IPR), the necessity to comply with regulatory and industry standards, and the need for robustness, precision, accuracy, and reliability. As cost-effective environmental interventions have not been effectively implemented in India, and because distribution of aids and assistive devices are not effectively funded by the government, almost two thirds of those using assistive devices and rehabilitation technology have purchased the devices themselves from private sources.

Those left without assistive devices, or with old-fashioned and inefficient devices are the target for those who enter the market with ‘low cost’ devices, of dubious scientific or medical value, and poor regulatory compliance. As an under-served and under-supported sector, the assistive devices sector only benefits from innovations by those innovators who have spotted the niche funding opportunity and lack of robust competition in the so-called low cost indigenous market.

Three recent legal instruments have the potential to significantly improve the access of good quality assistive devices for the disabled India. The instruments, arriving nearly together, set up formidable barriers to poor research and engineering, and non-standard assistive devices being distributed to unwary persons with disability who are in want and discomfort. These are The Rights of Persons with Disability Act, 2016, The Medical Devices Rules, 2017 and The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

This Policy Report takes stock of the compliance and regulatory environment in India, critically examines the legal ecosystem relating to research and ethics of clinical trials for assistive devices. It also analyses the gaps in the ethical conduct of research and concludes by highlighting the need to streamline research protocols in order to serve the disability sector in an effective manner.

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My experience as the Member – Legal of several Institutional Human Ethics Committees including those of IIT-Madras, National Institute of Epidemiology - ICMR, SRM Institute of Medical Sciences, SRM Medical College, and National Institute of Siddha, helped me develop and refine my understanding of the role of research in improving the lives of people, and the importance of regulatory standards and compliances with legal requirements in the conduct and monitoring of such research. For this, I wish to express my thanks and also my appreciation for the commitment demonstrated by the members of these committees towards ethical conduct of research.

I. DISABILITY IN INDIA – A STATISTICAL PERSPECTIVE

Statistics regarding the prevalence of disabilities vary widely depending on the reliability of statistics and the difference in the manner of collection of the data. According to the World Health Organisation's World Report on Disability¹, 15 per cent—about one billion people—of the world's population lives with some form of disability of whom, 2-4 per cent experience significant difficulties in functioning. The Global Burden of Disease that assesses mortality and disability estimates a figure of around 19.4 per cent² of the global population as having disabilities, and around 3.8 per cent having severe disability. All reports agree that the global estimate for disability is witnessing a rise due to populations ageing and the rapid spread of chronic diseases, as well as improvements in methodologies used to measure disabilities.

The World Report on Disability also states that disability disproportionately affects vulnerable populations. Results from the World Health Survey indicate a higher disability prevalence in lower income countries and people from the poorest wealth quintile; women and older people also have a higher prevalence of disability. Multiple Indicator Cluster Surveys in selected countries show that children from poorer households and those in ethnic minority groups are at significantly higher risk of disability than other children. Increasing evidence suggests that people with disabilities experience poorer levels of health than the general population and may experience greater vulnerability to preventable secondary conditions, co-morbidities, and age-related conditions. In many low-income and middle-income countries, only 5-15 per cent of people who require assistive devices and technologies have access to them³. Mukesh Jain, Joint Secretary, Department of Disability Affairs, Government of India, stated that prevalence of disability was much higher in rural areas than in urban areas, among men more than women, and that movement disability was the most significant⁴ disability.

¹ **World Health Organization. 2011.** "[World Report on Disability](http://apps.who.int/iris/bitstream/handle/10665/70670/WHO_NMH_VIP_11.01_eng.pdf;jsessionid=57DF2CEDE69819B128C1F1457A6B01CC?sequence=1)".

[http://apps.who.int/iris/bitstream/handle/10665/70670/WHO_NMH_VIP_11.01_eng.pdf;jsessionid=57DF2CEDE69819B128C1F1457A6B01CC?sequence=1].

² **Herricks. J. R. et al. 2017.** "The global burden of disease study 2013: What does it mean for the NTDs?", *PLoS Negl Trop Dis*, August 3. Vol. 11, Issue. 8. [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5542388/>].

³ **World Health Organization. 2018.** "[Disability - Assistive devices and technologies](http://www.who.int/disabilities/technology/en/)". [<http://www.who.int/disabilities/technology/en/>].

⁴ **Healthcare Innovation. 2015.** "[India needs assistive technologies for people with disabilities](https://www.enterpriseinnovation.net/article/india-needs-assistive-technologies-people-disabilities-390330408)", February 18. [<https://www.enterpriseinnovation.net/article/india-needs-assistive-technologies-people-disabilities-390330408>].

What health problems cause the most disability?



Source: <http://www.healthdata.org/india>

Data from the Global Health Data Exchange⁵ list some of the significant disabling conditions that are not assessed as disability in India.

The lack of rigorous and comparable data on disability and evidence on programmes that work, impede understanding and action in India. The latest and most definitive statistics from India on the number of persons with disabilities is the 2011 census, which points out that 2.68 Crore persons, amounting to 2.21 per cent of the population, are disabled⁶. However, the World Bank report, *People with Disabilities in India: From Commitments to Outcomes*⁷, July 2009, prepared at the request of the Government of India, estimated that people with disabilities comprised between five and eight per cent of the Indian population (around 55-90 million individuals at that time). The report found that only about 20 per cent of persons with disabilities in the National Sample Survey's 58th Round had ever been advised aids and appliances and less than 16 per cent had acquired any such aids and appliances. Women with disability are less likely to receive aids and appliances.

⁵ Institute for Health Metrics and Evaluation, University of Washington. 2018. "[Global Health Data Exchange](http://ghdx.healthdata.org/)". [http://ghdx.healthdata.org/].

⁶ Social Statistics Division, Ministry of Statistics and programme Implementation, Government of India. "[Disabled Persons in India, a statistical profile 2016](http://mospi.nic.in/sites/default/files/publication_reports/Disabled_persons_in_India_2016.pdf)". [http://mospi.nic.in/sites/default/files/publication_reports/Disabled_persons_in_India_2016.pdf].

⁷ The World Bank. 2009. "[People with Disabilities in India: From Commitments to Outcomes](http://documents.worldbank.org/curated/en/577801468259486686/pdf/502090WP0Peopl1Box0342042B01PUBLIC1.pdf)", July. [http://documents.worldbank.org/curated/en/577801468259486686/pdf/502090WP0Peopl1Box0342042B01PUBLIC1.pdf].

Persons with disability routinely report several barriers and challenges to good quality of life, including inadequate policies and standards, and poor implementation and enforcement of existing policies and standards. Beliefs and prejudices constitute barriers to education, health care, and social participation. Misconception by employers that people with disabilities are less productive and that reasonable accommodation is expensive for employers limits employment opportunities. The World Report on Disability⁸ found that high cost and lack of provision of services near them were the most frequent reasons for people with disabilities not using health facilities in Tamil Nadu. Additionally, poor coordination of services, inadequate staffing, and weak staff competencies negatively affect quality, accessibility, and adequacy of services.

The lack of effective financing is also a major obstacle to sustainable services in low- and middle-income countries. Built environments remain inaccessible and lack of access to transportation is a frequent reason for persons with disability being discouraged from seeking work or prevented from accessing health care. People with disabilities have significantly lower rates of information and communication technology use than non-disabled people, and in some cases, they may be unable to access even basic products and services such as telephones, television, and the Internet.⁹ Often, many people with disabilities are excluded from decision-making in matters directly affecting their lives.

All these factors impact their participation in clinical trials and research. Inability to access standard health care may encourage them to participate in trials where they are assured of better standard of care; inability to exercise autonomous decision-making capacity with regard to participation may force them into participating involuntarily or discourage them from a potentially beneficial clinical trial.

Cultural Perspective of Disability

Claims are made that Indian heritage viewed persons with disability as a part of and contributing members of the larger society in the early centuries of the Common Era. Records claim that there were workshops set up for persons with disabilities during the Gupta Period¹⁰. Kautilya is reported

⁸ *World Health Organization*. 2011. "[World Report on Disability](http://www.who.int/disabilities/world_report/2011/report.pdf?ua=1)", pg. 63. [http://www.who.int/disabilities/world_report/2011/report.pdf?ua=1].

⁹ *World Health Organization*. 2011. "[World Report on Disability](http://www.who.int/disabilities/world_report/2011/accessible_en.pdf)". [http://www.who.int/disabilities/world_report/2011/accessible_en.pdf].

¹⁰ Narayan, J. 2004. "[Persons with Disabilities in India: A Special Educator's Personal Perspective](http://dsq-sds.org/article/view/485/662)", *Disability Studies Quarterly*, Spring 2004, Vol. 24, Issue. 2. [http://dsq-sds.org/article/view/485/662].

to have advised rulers that the indigent and persons with disabilities must be maintained at state expense; Emperor Ashoka is said to have provided maintenance to persons of inadequate means, widows and persons with disability¹¹. Rulers, philosophers and poets with disabilities are said to have been accepted in society since they are remembered in the epics (the visually impaired Dhritarashtra of *Mahabharata*), and their works—Surdas, the poet, was visually impaired. Indian religions taught that service for persons with disability granted *punya*; for those without disability, disability in society offers a chance to develop charity and good karma for the next life. However, as A.L. Basham points out, persons with disability in our epics are associated with acts of mischief (Shakuni in the *Mahabharata*), having *mala fide* intentions (Manthara, the maid of Kaikeyi), or are incompetent and undeserving (Dhritarashtra)¹². Kautilya also was a forerunner in employing dwarves, hunchbacked persons, and persons with deformities as spies and informers¹³.

In India, culturally driven negative attitudes towards disability in general and persons with disability in particular have adversely impacted the development of rehabilitation engineering and assistive devices. Hindus believe that, according to the law of karma, disability is a punishment for past misdeeds¹⁴. Households with persons with disabilities also consider themselves punished. However, this primary negativity is sustained and enhanced by social and economic factors, such as the catastrophic and impoverishing impact of out-of-pocket health expenditures even in non-disabled lower income households. Improving quality of life for persons with disability and enhancing their participation was not encouraged in Indian culture. The first regular school for the visually impaired was established in Amritsar in 1887 by Annie Sharp. The school continues to function in its Dehradun premises where they shifted in 1902. The first and oldest formal school for the hearing impaired was established in Bombay in 1885 by an association of liberals and the philanthropist Vicar Apostolic, Dr. Leo Meurin¹⁵.

The ambiguity of Indian society towards acceptance of persons with disabilities as part of human diversity persists. As recently as on December 27, 2015, the Prime Minister, in his monthly address,

¹¹ “Social and Political Philosophy of The Welfare of The Disabled in India, Chapter – III”.

[http://shodhganga.inflibnet.ac.in/bitstream/10603/84924/14/14_chapter-iii.pdf].

¹² Basham, A. L. 1924. *The Wonder that was India*, London, Sedgwick and Jackson Press.

¹³ ‘...servants such as have taken the appearance of a hump-backed person, a dwarf, a pigmy (*kirata*), the dumb, the deaf, the idiot, the blind...shall espy the private character of these officers...’ Full Text of Kautilya’s Arthashastra, [https://archive.org/stream/in.ernet.dli.2015.276669/2015.276669.Kautilyas-Arthasastra_djvu.txt].

¹⁴ Gupta, V.B. 2011. “How Hindus Cope with Disability”, *Journal of Religion, Disability and Health*, Vol. 15, Issue. 1.

[<https://www.tandfonline.com/doi/citedby/10.1080/15228967.2011.540897?scroll=top&needAccess=true>].

¹⁵ Disability Status – India. 2003. “Hearing Impairment”. [<http://www.rehabcouncil.nic.in/writereaddata/HI-2-2003.pdf>].

Mann Ki Baat, advocated the use of *Dinyaang*—persons having some divine abilities in their limbs—in place of *Viklaang*—maimed or crippled. Several organisations, including the National Platform for the Rights of the Disabled, objected to the new terminology¹⁶ stating that the use of such patronising terms would not lead to any change in the lives of the people. It would not address the stigma and discrimination they face and the marginalisation they encounter. Again, the attribution of divinity would not address issues of equality and dignity; on the contrary, it would tend to create myths and further exclusion.

The social stratification in India, purportedly based on birth and, in turn, bound by the law of Karma, accommodates persons with disability at a lower level of the ladder to moksha than others on the same social hierarchy without disability. It is presumed that persons with disability are in perpetual misery and pain as they repair their karma. They can rest happy in the knowledge that in their next life they will be whole and happy. Unfortunately, this absurd and unproved (and unprovable) line of reasoning seems to have made itself at home even in scientific institutions. The Society for Biomedical Technology (SBMT), a collaboration between the Defence Research and Development Organisation (DRDO), the Department of Rural Development, and Ministry of Welfare, is a vehicle to provide indigenous solutions in the field of medical and healthcare equipment and devices using spin off technologies from defence R&D. The founder-chairman of SBMT is the late former President, A.P.J. Abdul Kalam, whose statement ‘Let my brain relieve your pain’, is emblazoned on the banner of the website¹⁷. The statement, a part of his ‘Oath for Doctors’¹⁸, is rife with presumption and innuendo—in particular the implication that those in need of care are constantly in pain waiting to be relieved—the healthcare equivalent of the patriarchal trope of damsel in distress.

This belief is incomprehensible to persons who have not encountered it in their formative years. Writing about her experience in Cambodia, a country that also believes in karmic outcomes, Megan Smith, a volunteer for UNICEF’s Local Governance for Child Rights programme, believes that the difficulties and prejudices she faces are not due to her disability but due to a society that is not

¹⁶ **National Platform for the Rights of the Disabled. 2016.** “[Copy of a letter addressed to Prime Minister Shri Narendra Modi](http://feministlawarchives.pldindia.org/wp-content/uploads/Letter-to-PM-by-National-Platform-for-the-Rights-of-the-Disabled.pdf)”, January 22. [http://feministlawarchives.pldindia.org/wp-content/uploads/Letter-to-PM-by-National-Platform-for-the-Rights-of-the-Disabled.pdf].

¹⁷ **Society for BioMedical Technology. 2007.** “[A brief details of the projects undertaken by SBMT](http://www.sbmtindia.org/activities/)”. [http://www.sbmtindia.org/activities/].

¹⁸ **abdulkalam.com. 2001-16.** “[Oath for doctors](http://www.abdulkalam.com/kalam/theme/jsp/oath/oath_doctors.jsp)”. [http://www.abdulkalam.com/kalam/theme/jsp/oath/oath_doctors.jsp].

accessible¹⁹. She is appalled by the commitment to suffering and acceptance of an inequitable society by Cambodians with disability. Social culture promotes the perception that persons with disability are in a perpetual state of misery and pain and that it is their rightful and natural condition. Unfortunately, finding themselves at the receiving end, some Indians with disability are also in alignment with the thought and prefer acceptance as a way to building better karma. They also accept life as objects of pity and charity.

Studies have shown that sadness and misery are as prevalent in persons without disability as in persons with disability. The Hedonic Adaptation theory²⁰ states that regardless of what happens to someone (winning a lottery/losing a limb), their level of happiness with return to their baseline after the event. The baseline is individualised and individual differences in rates and extent of adaptation are significant. There are internal circumstances under a person's voluntary control which, if altered, could lead to a different baseline of happiness. Attempts have also been made to explain happiness as a state of surplus energy²¹ through association with good metabolism and glucose levels, social support, goal achievement, social support and wealth, and respect for human rights in the country where the person is resident. In fact, the level of pain or misery persons with disability undergo in India is directly attributable to the stigma and marginalisation they encounter in accessing necessary health care and rehabilitation support, and an inaccessible environment, exacerbated with scant respect for human rights or for the person.

The foregoing is important to understand why persons with charitable intentions and poor scientific capabilities, compounded by their almost arrogant non-compliance of known scientific and legal regulatory mechanisms enter the field of rehabilitation engineering and assistive devices. Since cost-effective environmental interventions have not been effectively implemented in India, and because distribution of aids and assistive devices are not effectively funded by the government, almost two-thirds of those using assistive devices and rehabilitation technology have purchased the devices themselves from private sources. The assistance to buy aids and appliances fall within a range of individual beneficiary schemes that have serious implementation problems and low coverage. In addition, systems for support and maintenance of assistive devices remain under-

¹⁹ Smith, M. 2015. "[Disabling karma: Reflections on Buddhism, disability and charitable drive-bys](https://blogs.unicef.org/blog/disabling-karma-reflections-on-buddhism-disability-and-charitable-drive-bys/)", UNICEF, December 3. [https://blogs.unicef.org/blog/disabling-karma-reflections-on-buddhism-disability-and-charitable-drive-bys/].

²⁰ First explained by Brickman and Campbell in, *Hedonic Relativism and Planning the Good Society*, (1971). In M. H. Appley (Ed.), *Adaptation-level theory* (pp. 287-305). New York: Academic Press.

²¹ Gailliot, M. T. 2012. "[Happiness as Surplus or Freely Available Energy. Psychology](https://www.scirp.org/journal/PaperInformation.aspx?PaperID=22768)", *Scientific Research*, Vol.3. No.9. [https://www.scirp.org/journal/PaperInformation.aspx?PaperID=22768].

developed, further increasing the cost of the device. A vicious circle of unemployment and lower income leading to financial barriers to access assistive devices to overcome environmental barriers, which leads to lower likelihood of employment, has trapped persons with disability and also households with disability. Those left without assistive devices, or with old-fashioned and inefficient devices, are the target for those who enter the market with 'low cost' devices of dubious scientific or medical value and poor regulatory compliance.

Consider this: The only reason that the Jaipur Foot, admittedly inferior to today's carbon fibre foot prosthetics, continues to be popular is owing to its low cost. Anyone who can pay for or be fortunate enough to receive an Ottobock Triton, an Echelon Endolite, or an INR 5.5 Lakh Freedom Foot²² would not choose a Jaipur Foot. This brings into question whether the fact that benefiting an estimated 1.55 million people with disabilities makes Jaipur Foot a 'popular' prosthetic. The indigenous design, first developed in 1968, was intended for 'rural people'.

According to their website²³, the Jaipur Foot was developed to meet the socio-cultural needs of handicapped people in India—squatting, sitting cross-legged, walking on uneven terrain, working in muddy fields, and walking without shoes. The then available European and U.S. versions, the SACH and the Seattle Foot, could not provide the required dorsiflexion of the ankle to permit these positions and movement. However, in the years since, top-range, state-of-the-art prosthetic feet can provide more support and movement than the Jaipur Foot. Unfortunately, Indian writers on prosthetics continue to promote the Jaipur Foot as the best option on the ground of its low cost. A 2018 U.S. review²⁴ of commonly used prosthetic feet in developing countries found that only the Niagara Foot and the 'Shape and Roll (S&R)' Foot have passed ISO-10328 testing. Despite its long lifespan (2-5 years), Jaipur Feet were found to undergo the greatest deformation, which would result in early knee flexion during walking and knee collapse proximal to the knee joint for amputees. Under-standardised production practices led to defective craftsmanship in 56 per cent of cases for the Jaipur Foot, including leg length asymmetries. Inadequate foot fitting resulted in non-optimal walking and suspension. Over half the pain reported from use of Jaipur foot was attributed to these errors. Only half the amputees were actually able to sit cross-legged

²² Singh, J. 2015. "[Artificial reality](http://www.downtoearth.org.in/news/artificial-reality-40337)", DownToEarth, July 4. [http://www.downtoearth.org.in/news/artificial-reality-40337].

²³ Bhagwan Mahaveer Viklang Sahayata Samiti, Jaipur. 2016. "[HOW WE DO-Technology](http://jaipurfoot.org/how_we_do/technology.html)". [http://jaipurfoot.org/how_we_do/technology.html].

²⁴ Laferrier, J. Z. et. al. 2018. "[A Review of Commonly Used Prosthetic Feet for Developing Countries: A call for Research and development](https://www.omicsonline.org/open-access/a-review-of-commonly-used-prosthetic-feet-for-developing-countries-acall-for-research-and-development-2165-7025-1000380.pdf)", *Journal of Novel Physiotherapies*, February 27. [https://www.omicsonline.org/open-access/a-review-of-commonly-used-prosthetic-feet-for-developing-countries-acall-for-research-and-development-2165-7025-1000380.pdf].

and approximately 60 per cent were able to squat. About 38 per cent users reported discomfort at even low to moderate activity.

Further, in 1994, Dr B.N. Prasad, chief of Orthopaedics at the Nizam Institute of Medical Sciences (NIMS), Hyderabad, visited the DRDO's Composite Product Centre hoping to borrow missile technology for correcting skeletal deformities in children²⁵. This was followed by Kalam's visit to NIMS where he observed children with residual paralysis resulting from polio infection. The children were using metal and leather orthoses that were first developed in the mid-19th Century, each weighing up to 3 kg. Kalam was instrumental in encouraging development, at DRDO, of polypropylene thermoformed Floor Reaction Orthoses (FRO) weighing about 300 gm. It is important to note that flexible plastic shell-type orthoses made of polypropylene were first introduced around 1970²⁶ and thermoformed orthoses were in use since the 1960s²⁷. The product was manufactured and marketed by Artificial Limb Manufacturing Corporation of India (ALIMCO). The calipers were in modular form and available in various sizes.

The astoundingly poor engineering design and outcome were far below the state-of-the-art even by the standards of 1994. In 1989, Blatchford had come up with a custom fitted lightweight modular orthosis for use in the early stages of rehabilitation. The orthoses industry was aware as early as the mid-18th century that orthoses must be created specifically to cater to the persons' size, weight, and particular orthotic condition and movement constraints for the best outcome. The leather and metal braces of earlier times were customised or custom-made for persons with disability based on a prescription. Today, manufacturing and fitting the appropriate orthoses are a product-and-service domain. The manufacturer and the orthotic specialist focus on fusing the custom-made physical product with accompanying services and monitoring to enable the customer to benefit from longer lasting, better fit, and comfort. Instead of undertaking the engineering, design, and customisation work required, the project designed a single piece product of standard sizes and modular components to allow for basic fitting. Such orthoses are currently used to help clinicians identify and prescribe the right orthoses for their patients. Yet again, it was the argument that the device was 'low cost', which, apart from the brand value of the DRDO and Kalam, allowed

²⁵ Menon, A. K. 1994. "[Spin-offs from defence technology help polio victims](https://www.indiatoday.in/magazine/indiascope/story/19940715-spin-offs-from-defence-technology-help-polio-victims-809390-1994-07-15)", *India Today*, July 15. [https://www.indiatoday.in/magazine/indiascope/story/19940715-spin-offs-from-defence-technology-help-polio-victims-809390-1994-07-15].

²⁶ Showers, D. C and Strunck, M. L. 1984. "[Sheet Plastics and Their Applications in Orthotics and Prosthetics](http://www.oandplibrary.org/op/1984_04_041.asp)", *Digital Resource Foundation for the Orthotics & Prosthetics Community*, Vol. 38, Issue. 4, Pg. 41-48. [http://www.oandplibrary.org/op/1984_04_041.asp].

²⁷ Ibid.

extensive and unregulated use of the device. The devices were used by an estimated 50,000 people with disabilities. According to reports, ALIMCO has stopped manufacturing the devices as of 2013²⁸. It is suggested that better use of the funds could have been made if the devices had been better designed and trialled as per regulatory standards. Another possible better outcome would have been to enter into an agreement with companies providing standard equipment and devices to import or manufacture under license in India. The license could have covered upgrades, spares, and training in fitting and maintenance.

The World Health Organisation (WHO) defines assistive devices and technologies as those whose primary purpose is to maintain or improve an individual's functioning and independence to facilitate participation and to enhance overall well-being²⁹. They can also help prevent impairments and secondary health conditions. Examples of assistive devices and technologies include wheelchairs, prostheses, hearings aids, visual aids, and specialised computer software and hardware that increase mobility, hearing, vision, or communication capacities. Developing useful and usable assistive devices requires input from multiple disciplines and sectors, including involvement and participation of persons with the specific disability that the team is working to support. The rehabilitation engineering and assistive technology market is driven globally by government initiatives, and national policies and programmes. Advancements in health care facilities and awareness regarding assistive devices technologies in the relevant populations, supported by technological advancement in many areas, including software, communications technologies, and material sciences, push the pace of device development.

WHO Standards for Orthotics and Prosthetics³⁰ point out the responsibility of states to promote the use of prostheses and orthoses at a cost that is affordable to users or to the state. It recalls that governments should assume a leading role for the governance of prosthetics and orthotics services and should involve a range of stakeholders in planning, developing, and monitoring services. A guiding framework, consisting of legal acts, policies, strategic plans, standards, rules, and regulations should be in place to guide the design of affordable, accessible, effective, efficient, and safe services of high quality. Products and working methods should be appropriate to the setting

²⁸ **Krishan, S. R. 2015.** "[No takers for Kalam's low priced stents](http://www.sunday-guardian.com/news/no-takers-for-kalams-low-priced-stents)", *The Sunday Guardian*, August 1. [http://www.sunday-guardian.com/news/no-takers-for-kalams-low-priced-stents].

²⁹ **World Health Organization. 2018.** "[Disability and rehabilitation: Assistive devices and technologies](http://www.who.int/disabilities/technology/en/)". [http://www.who.int/disabilities/technology/en/].

³⁰ **World Health Organization. 2017.** "[Standards for Prosthetics and Orthotics, Part 1: Standards](http://apps.who.int/iris/bitstream/handle/10665/259209/9789241512480-part1-eng.pdf;jsessionid=C664D1DDFC7934C23F44E800D622F421?sequence=1)". [http://apps.who.int/iris/bitstream/handle/10665/259209/9789241512480-part1-eng.pdf;jsessionid=C664D1DDFC7934C23F44E800D622F421?sequence=1, 2017].

in which the products are fabricated, fitted, used, and funded. A national list of priority products should be made, which would help to mobilise resources, guide product development, and simulate competition. India, like many other countries, does not have national prosthetics or orthotics standards. The WHO insists that state regulation is central to increasing access to safe, effective, high-quality prostheses and orthoses. As these are health products, a regulatory system is best established as an integral part of national health care regulation. The recommended standards are ISO or equivalent structural requirements for testing of strength, durability, and safety, and clinical field tests to ensure fitness for the purpose. Scientific testing methods are recommended for reliability, validity, and comparability of results globally. A part of the standards cover implementation and cast a duty on the governments to ensure that prosthetics and orthotics services are provided only by qualified providers. Significantly, the WHO introduces the concept of cost-effectiveness, which is ‘a measure of responsible use of the available funds...Efficiency is, therefore, necessary for equity in service delivery’. The WHO advocates that various cost-sharing arrangements should be put in place, including social insurance and cost proportional to amount of care consumed.

India has not developed standards in the area of product or services relating to prosthetics and orthotics. Many organisations—private/public, entrepreneurial, and social entrepreneurial—are developing technology solutions through sponsored or self-funded research in rehabilitation engineering and assistive devices. Collaborations such as SAATH (Seamless Affordable Assistive Technology for Health) are also emerging. SAATH is a collaboration between IIT Kanpur, IISc Bangalore, KTH Sweden, and Gavle University, involved in developing physical activity monitoring and diagnostic tools for assessing the mobility and motor skills of elderly persons. The TTK Centre for Rehabilitation Research and Device Development Lab (R2D2) is a TTK Health Care supported lab at IIT Madras. The group is involved in research related to human movement, the influence of orthotic and prosthetic devices on movement, and in the design and development of assistive devices for persons with impairments. Start-ups are enthusiastically attempting to convert good intentions and technological competence into sector specific assistive devices—Tellmate, a pair of wearable glasses that process images, convert them into sound, and whisper it into the ear using hearing aids; Braille Me, an input-output device where content can be read and typed, and FJ Typer, which is a training tool to help children with poor vision³¹.

³¹ **Mandavia, M.** 2017. “[How a bunch of Indian tech startups hope to change the world for the visually impaired](https://economictimes.indiatimes.com/small-biz/startups/fledgling-assistive-technology-space-gets-help-from-startups/articleshow/59100127.cms)”, *The Economic Times*, June 12. [https://economictimes.indiatimes.com/small-biz/startups/fledgling-assistive-technology-space-gets-help-from-startups/articleshow/59100127.cms].

However, in general, Indian innovators in assistive device technology lack crucial understanding of the market realities. It appears that innovators have, at best, a rather sketchy understanding of issues like freedom-to-operate and infringement of Intellectual Property Rights (IPR), regulatory and industry standards and the necessity to comply with them, and the need for robustness, precision, accuracy and reliability for use by the disability sector. Yet, these projects also win awards and funding from public and private bodies and programmes, such as the DST-Lockheed Martin India Innovation Growth Programme (IIGP), the Wellcome Trust, and the state and central governments. As an underserved and under-supported sector, the assistive devices sector only benefits from innovations by those innovators who have spotted the niche funding opportunity and lack of robust competition in the so-called low cost indigenous market.

On a random selection, this Report selected Tellmate—the wearable glasses that convert visual image to speech. The project won the 2016 DST-Lockheed Martin IIGP Award and benefited from some INR 25-50 Lakhs worth of funding for development of the project and an incubation opportunity at IIM Ahmedabad. Their page inviting interns³² helpfully informs candidates that Tellmate Helper Private Limited is today a DIPP-recognised start-up and has won the MEA-NITI Aayog Contest on social innovation and was also featured on *Mann Ki Baat*. Their latest version is available as a smartphone app, which appears to have the ability to take pictures using a mobile phone camera, crop the image to focus on specific text/image, upload the selected content to their server, and receive the synthesised content in speech format. It requires great precision in taking the appropriate photograph, cropping/editing it to the required focus area, and waiting for the server to respond.

In essence, the technology is a software application—an app—that is built of components such as mobile optical character recognition (OCR) that enable on-the-go access to printed documents such as restaurant menus, bills, or signs on walls. The efficiency of the outcome is driven by the processing power of smartphones, the imaging characteristics and the high resolution of phone cameras, and the maturity of OCR algorithms. The limitations of OCR for use in assistive devices is the requirement of a well-framed image of the text at good resolution—poor resolution, wrong angle of orientation of the camera or camera phone, and writing that is not clean/crisp text could reduce the usability of the technology with persons with visual impairment. Persons unable to see the mobile screen or unable to hold the mobile steady would not be able to capture a good picture

³² Internshala. 2018. “[Embedded Systems Internship in Jaipur at Tellmate Helper Private Limited](https://internshala.com/internship/detail/embedded-systems-internship-in-jaipur-at-tellmate-helper-private-limited1521311103)”. [https://internshala.com/internship/detail/embedded-systems-internship-in-jaipur-at-tellmate-helper-private-limited1521311103].

for processing. Some accessibility apps like Text Detective capture images continuously and process the readable text as soon as it is detected³³. Tellmate is impaired by these limitations of over-the-counter technology components and their rate of interoperability. For instance, while comparable apps like Text Detective require no internet connection and process the image using the phone's processing capacity, Tellmate requires the text to be uploaded to a server for processing. The technology components are free for download for developers and are provided under an End User License Agreement (EULA) that have different license agreements for product commercialisation or may be covered under licenses that require the product to be used in conjunction with specific platforms.

In any case, those interested in such a pair of miracle glasses as attempted by Tellmate could try the US\$ 3500 OrCam MyEye, a breakthrough wearable artificial vision device, which is a tiny lightweight camera mounted on a pair of glasses that can intuitively, instantly, and discreetly read printed text and digital text aloud, and interpret faces, currency notes, and products (using a database of barcodes). OrCam understands gestures and is triggered by a simple pointing gesture. The OrCam wearable is built by the founders of Mobileye—pioneers in autonomous cars—subsequently acquired by Intel. The OrCam patent³⁴, filed in 2012, covers a visual assistance device wearable by a person that includes a camera and a processor. The processor captures multiple image frames from the camera. A candidate image of an object is searched in the image frames, classified as an image of a particular object or in a particular class of objects, and is thereby recognised. The person is notified of an attribute related to the object. OrCam is also the assignee of the gestural interface invention of Pranav Mistry and Patricia Maes, of the MIT Media Lab. The MIT Media Lab is at the forefront of wearable computing, wireless communications, machines with common sense, and learning technologies. The technology recognises gestures, including pointing at objects in the users' environment and interacting with graphical interfaces.³⁵

The illustration demonstrates that technology dependence is determined by those in control over Intellectual Property assets. The platform dependency of devices ensures that the company that owns software platform and the hardware ensures that products cannot be sold without the intellectual property value being repatriated to the companies that own them. Costing then,

³³ iaccessibility.com. "[Text Detective](https://www.iaccessibility.com/apps/low-vision/index.cgi/product?ID=60)". [https://www.iaccessibility.com/apps/low-vision/index.cgi/product?ID=60].

³⁴ *Espacenet Patent search*. "[Bibliographic data: EP2490155 \(A1\) — 2012-08-22](https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2490155A1&KC=A1&FT=D)". [https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2490155A1&KC=A1&FT=D].

³⁵ *IFI Claims Patent Services*. 2009. "[Wearable Gestural Interface](https://patents.google.com/patent/US20100199232A1/en)", February 3. [https://patents.google.com/patent/US20100199232A1/en].

according to the WHO standards, can be reduced significantly by some government steps such as reducing/waiving import taxes on components, materials, tools, machines and other equipment, and inclusion of services to support early detection, early treatment, and prevention of secondary impairments.

The global elderly and disabled assistive devices market³⁶ is fragmented with high competition among the players. In spite of this, the market is predicted to touch US\$ 19,684.9 million in 2019³⁷ and US\$ 26 billion by 2024³⁸. The wheelchair market, under medical mobility aids and ambulatory devices, is in a dominant position. Geographically, the U.S. leads the market owing to the fact that numerous market players are based in the U.S. On the other hand, a number of Asian countries, such as China, India, and Japan, will be experiencing the most exponential development in the market in the coming years due to rising disposable incomes and increasing healthcare reforms in these countries. The Asia Pacific elderly and disabled assistive devices market is predicted to touch US\$ 5,051.1 million by 2019. According to *The Times of India*, the market size for assistive devices in India is about INR 4,500 crores³⁹.

A 2014 Infosys report⁴⁰ states that the Indian medical device industry is replete with challenges, including archaic regulatory standards, inadequate quality standards and non-compliance, high import dependency, meagre government funding to promote innovation, and lack of local talent. As much as 75 per cent of India's total demand for medical devices is currently met by imports, with nearly 30 per cent being supplied by the U.S. alone. As the U.S. is a leader in medical device innovation, there is a mismatch between the design of certain technologies being imported and the realities of clinical conditions and health care infrastructure existing in India.

³⁶ **Transparency Market Research.** 2016. "[Global Elderly and Disabled Assistive Devices Market: Wheelchairs Spend in U.S. is Highest Globally](https://www.transparencymarketresearch.com/pressrelease/elderly-disabled-assistive-devices-industry.htm)" October. [https://www.transparencymarketresearch.com/pressrelease/elderly-disabled-assistive-devices-industry.htm].

³⁷ **PR Newswire.** 2014. "[Elderly And Disabled Assistive Devices Market - Global Industry Analysis, Size, Share, Growth, Trends & Forecast to 2019](https://www.prnewswire.com/news-releases/elderly-and-disabled-assistive-devices-market---global-industry-analysis-size-share-growth-trends--forecast-to-2019-256673091.html)", April 25. [https://www.prnewswire.com/news-releases/elderly-and-disabled-assistive-devices-market---global-industry-analysis-size-share-growth-trends--forecast-to-2019-256673091.html].

³⁸ **McCue, TJ.** 2017. "[Elderly And Disabled Assistive Technology Market To Surpass \\$26 Billion By 2024](https://www.forbes.com/sites/tjmccue/2017/03/21/elderly-and-disabled-assistive-technology-market-to-surpass-26-billion-by-2024/#3e33277969ea)", *Forbes*, March 21. [https://www.forbes.com/sites/tjmccue/2017/03/21/elderly-and-disabled-assistive-technology-market-to-surpass-26-billion-by-2024/#3e33277969ea].

³⁹ **Debroy, S.** 2016. "[Market size of assistive technology for persons with disability is Rs 4500 crore](https://timesofindia.indiatimes.com/business/india-business/Market-size-of-assistive-technology-for-persons-with-disability-is-Rs-4500-crore/articleshow/51062327.cms)", *The Times of India*, February 20. [https://timesofindia.indiatimes.com/business/india-business/Market-size-of-assistive-technology-for-persons-with-disability-is-Rs-4500-crore/articleshow/51062327.cms].

⁴⁰ **Peter, D.** "[Indian Medical Device Industry – Current State & Opportunities for Growth](https://www.infosys.com/consulting/insights/Documents/indian-medical-device-industry.pdf)", Life Sciences and Services, Infosys Consulting. [https://www.infosys.com/consulting/insights/Documents/indian-medical-device-industry.pdf].

The Emerging Ecosystem for Assistive Devices in India

Three recent legal instruments are set to alter the assistive devices scene in India. The instruments, arriving nearly together set up formidable barriers to poor research and engineering, and non-standard assistive devices being distributed to unwary persons with disability who are in want and discomfort. These are:

a. The Rights of Persons with Disability (RPWD) Act, 2016

The RPWD Act, 2016, is an Indian enactment to give effect to the UN Convention on the Rights of Persons with Disabilities (UN CRPD). The CRPD is an international human rights treaty of the United Nations intended to protect the rights and dignity of persons with disabilities. Parties to the Convention are required to promote, protect, and ensure the full enjoyment of human rights by persons with disabilities and ensure that they enjoy full equality under the law. The Convention has served as the major catalyst in the global movement: It has been instrumental in bringing about a change perspective, from viewing of persons with disabilities as objects of charity, medical treatment, and social protection to viewing them as full and equal members of society, with human rights who are capable of claiming those rights and making decisions for their lives based on their free and informed consent as well as being active members of society. To date, 177 countries, including India, have ratified the treaty. The treaty also provides a framework for inclusion of the Sustainable Development Goals. The 2030 Agenda for Sustainable Development clearly states that disability cannot be a reason or criteria for lack of access to development programming and realisation of human rights. The Sustainable Development Goals framework includes seven targets, which explicitly refer to persons with disabilities, six further targets on persons in vulnerable situations, which include persons with disabilities.

The RPWD Act protects persons with disabilities from being included as participants in trials without the permission for the Committee on Research on Disability and without written informed consent for participation. The Act urges respect for difference and acceptance of persons with disabilities as part of human diversity and humanity towards full and effective participation and inclusion in society. Government focus is driven towards universal design of built environment and consumer products, including electronics. Reasonable accommodation is to be provided by employers and government institutions are required to support and enable persons with high support needs to live independent and full lives.

b. The Medical Devices Rules, 2017

The Medical Device Rules, 2017, came into effect on January 1, 2018. The Rules have been framed in conformity with the Global Harmonisation Task Force Framework and conform to the best international regulatory practices to meet the requirement of the medical devices sector. Medical devices, classified according to risk category, will be required to meet proportionate regulatory requirements. The Rules also seek to evolve a culture of self-compliance by manufacturers through self-certification and post-approval audits. The Rules provide for separate regulations for clinical trials of investigational devices on par with international practices, to be regulated by the Central Drugs Standard Control Organisation. Trials are required to be conducted in a manner that helps realise the goals of both safety and welfare, and discovery and commercialisation of new devices. Medical management and compensation are provided for in the case of unexpected adverse events. The Rules seek to enable the creation of a robust ecosystem for all stakeholders, including innovators, manufacturers, providers, consumers, buyers, and regulators. Ambitiously, the Health Ministry expects the Rules to foster India-specific innovation and improving accessibility and affordability of medical devices across the globe by leveraging cost advantage of manufacturing in India.

c. The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

These guidelines, published by the Indian Council for Medical Research (ICMR), cover important areas of biomedical research and research involving human participants, including responsible conduct of research, informed consent process, vulnerability, biological materials, and research during humanitarian emergencies and disasters. The guidelines comprehend and attempt to address the socio-cultural ethos in India and the varying standards of healthcare while being sensitive to the social and natural environment. Expanding on the principles of non-maleficence, autonomy, beneficence, and justice, the guidelines enable researchers and sponsors to ensure that research and scientific experimentation are conducive and consistent with the dignity and well-being of participants. The guidelines also invite the participant to meaningfully engage with the community before, during, and after research to ensure greater responsiveness to their health needs and requirements. The scientist is required to be a responsible member of society and should ensure the protection of human and animal participants. The guidelines also provide extensive guidance on the formation and functioning of ethics committees, including the different types of review processes and management of adverse events.

Trial ethics are in an advanced stage of evolution globally. Many processes and protocols have been accepted as best practice. In India, testing of technology solutions for disabled persons need to be advanced significantly to bring it in alignment with globally acceptable standards (if not best practice) for such trials. With the growing interest in rehabilitation engineering and assistive technology devices among commercial groups such as TTK Healthcare, Appasamy Associates, Trivitron Healthcare, Aurolab—a division of Aravind Eye Care—and Wipro and others, trial ethics and responsible conduct of research becomes an important indicator of the commercial strategy and intent of the companies. On the other hand, failure to adhere to the regulatory requirements could lead to onerous liabilities, including imprisonment, fines and loss of reputation.

This study is intended to identify the gaps and irregularities in the current research and trial ecosystem and shed light on the intersection of the new legal instruments set to alter the research ecosystem in India.

II. CLINICAL TRIAL OF MEDICAL DEVICES IN INDIA

The Drugs and Cosmetics Act, 1940, regulates the import, manufacture, distribution and sale of drugs and cosmetics. Under the Act, the term ‘drug’ includes such devices intended for internal or external use in the diagnosis, treatment, mitigation, or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government⁴¹ after consultation with the Drugs Technical Advisory Board⁴². Notified devices (about 50) require registration before they can be sold in India. For other medical devices that do not require registration, the manufacturer can obtain a No Objection Certificate (NOC) from the Drug Controller General of India (DCGI). Foreign clinical data or testing reports may be considered to be sufficient for registration in certain cases; in other cases, the DCGI may require a clinical trial to be conducted in India in respect of the device.

Prior to 2005, no medical device regulations existed in India. Subsequently, the Central Drugs Standard Control Organisation (Medical Devices Division), on August 4, 2010, issued a Guidance Document on Requirements for Conducting Clinical Trial(s) of Medical Devices in India. Again, on July 12, 2016, the Ministry of Health and Family Welfare released a Draft Medical Device Rules, 2016. Finally, in exercise of its powers under Section 12 and 33 of the Drugs and Cosmetic Act, the Union Ministry of Health and Family Welfare notified the Medical Devices Rules, 2017, by notification dated January 31, 2017. The Rules came into effect on January 1, 2018.

The Rules introduce a new regulatory framework for clinical investigation of medical devices. The Rules cover several important aspects of research on rehabilitative and assistive devices. They provide helpful clarity in many areas that would ultimately help to improve outcomes in research in rehabilitative and assistive devices. Under the 2017 Rules, medical devices mean:

- a. Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time to time under the Drugs and Cosmetics Act, 1940 (“D&C Act”). Some categories of devices have already been notified by the government. A list of classes of currently notified medical devices is annexed as Annexure D;

⁴¹ Section 3(b)(iv); Under Rule 3(zb) of the Medical Device Rules, 2017, a ‘medical device’ means (C) devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act.

⁴² Constituted under Section 5.

- b. Specific substances intended to affect the structure or any function of the human body which are notified by the government. At present, the substances notified are mechanical contraceptives (eg. condoms, intrauterine devices, tubal rings) and disinfectants;
- c. Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;
- d. Substances used for in vitro diagnosis (referred to in the 2017 Rules as “In Vitro Diagnostic Medical Device”);
- e. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. This is a catch-all category for substances.

Only products that are covered by the definition of medical devices will be regulated by the 2017 Rules. A fixed timeline of 90 days has been prescribed for the licensing authority to arrive at a decision on application for permission to conduct clinical trial. Rule 3(a) defines ‘academic clinical study’ as a clinical study conducted for academic purpose on a medical device for

- 1. the approved or a new intended use,
- 2. new material or construction,
- 3. new improved design or
- 4. new population.

Interpretation of ‘academic clinical study’, as any clinical study undertaken towards the earning of a higher degree, or for a formal purpose, is erroneous. In fact, if towards the earning of a degree, a student undertakes clinical study that goes beyond the definition in section 3(a), it would not be an academic clinical study. Design that shall affect the quality in respect of its specifications, indication for use, performance, and stability of an approved medical device, is considered to be major change. Rule 51(3) states that no permission for conduct of academic clinical study on licensed medical device shall be required where the Ethics Committee has approved such a study and where the data generated during the study shall not be used to furnish to the Central Licensing Authority to manufacture or to import for marketing any investigational medical device in the country.

Before a device can be marketed for use by the general population in India, the CDSCO must approve it for use. To obtain this approval a device must undergo clinical investigation—a

systematic study of the investigational device in or on human participants to assess its safety, performance, or effectiveness⁴³. There must be clinical evidence to support the scientific validity and performance for the intended use of the device. This includes clinical data—the safety and/or performance information that is generated from the clinical use of the device. Clinical performance is the behaviour of a medical device or response of the subjects to that medical device in relation to its intended use⁴⁴, when correctly applied to appropriate patients.

Clinical data is collected from various sources:

1. clinical investigations of the investigational device;
2. other studies reported in scientific literature;
3. data relating to a similar device for which equivalence to the investigational device can be demonstrated;
4. published and/or unpublished reports on other clinical experience of either the investigational device or similar device for which equivalence to the investigational device can be demonstrated.

Clinical evaluation is a methodologically sound ongoing procedure to collect, appraise, and analyse clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's Instructions for use.

Assistive and rehabilitative devices are covered under the definition of 'active therapeutic devices'⁴⁵ in the Medical Devices Rules, 2017. The definition covers active medical devices, whether alone or in combination with any other medical device, to support, modify, replace, or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury, or handicap. Active medical devices are defined as medical devices that depend on a source of electrical energy or any other source of energy other than the energy generated by human or animal body or gravity.

⁴³ Rule 3(l). Under section 3(x) an investigational medical device is a device which does not have a predicate device, or one which is licensed for new use or new population, or major design change, and is being assessed for safety, performance or effectiveness. A predicated device (Rule 3(zm)) means a device, the first of its kind approved for manufacture for sale or for import by the CDSCO and has the similar intended use, material of construction, and design characteristics as the device which proposed for licence in India.

⁴⁴ 'Intended use' as per Rule 3(v) means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling or in the document containing instructions for use of such device or in promotional material relating to such device, which is as per approval obtained from the Central Licensing Authority.

⁴⁵ Rule 3(e).

Most assistive and rehabilitative devices, when mass produced, require ‘setting up’ of the device for specific body and overall condition of the user. For instance, a device such as crutches, if placed too low for body height, will result in excessive stress on the upper extremities; if placed too high, it would result in shoulder discomfort. Sometimes, an assistive or rehabilitative device may have to be ‘custom made’ in accordance with a written prescription of a registered medical practitioner for the sole use of a particular patient⁴⁶. Research in custom made devices require a prescription for the device to be used for a particular patient.

Classification of Devices

In tune with the global practice, the 2017 Rules will introduce a risk based classification system for regulation of medical devices. Rule 4 classifies devices as

- (i) low risk - Class A;
- (ii) low-moderate risk- Class B;
- (iii) moderate-high risk- Class C;
- (iv) high risk- Class D.

The classification is based on parameters specified in Part I of the First Schedule. Assistive devices that are non-invasive and come into contact with intact skin only are classified as Class A devices. Active devices would be classified as Class B. A long-term use medical device is assigned to Class D if it is an active medical device. Long-term use is defined as intended continuous use of the medical device for more than 30 days. According to Rule 7, the device shall conform to the standards laid down by the Bureau of Indian Standards or as may be notified by the Ministry of Health and Family Welfare, Government of India. Where no relevant standard of any medical device has been laid down, the device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC) or by any other pharmacopoeial standards. If the standards have not been specified, the device shall conform to the validated manufacturer’s standards.

Rule 93(1) prescribes debarment on account of submission of misleading information along with an application for grant of any license; the knowledge or intention of the applicant to mislead the authority is irrelevant. In order to comply with the regulatory requirements pertaining to clinical

⁴⁶ A ‘custom made medical device’ as per Rule 3(r) is a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialized in the relevant area, under his responsibility for the sole use of a particular patient, but does not include a mass production of such device.

trials, the investigator and the sponsor or institution must maintain and store documents and content related to the trial. While some countries require the maintenance of a Trial Master File (TMF), India has no specific requirement. The investigator is, however, required to maintain essential documents that enable the conduct of a trial and evaluation of the data produced.

Licenses granted under the Device Rules are perpetual, meaning that they will continue to be valid unless cancelled. When applying for a licence to import, manufacture, sell, or distribute a Class A device, the applicant must submit the following documents:

1. Device description, intended use of the device, specification including variants and accessories;
2. Material of construction;
3. Working principle and use of a novel technology [if any];
4. Labels, package inserts, user manual, wherever applicable;
5. Summary of any reported Serious Adverse Event in India or in any of the countries where device is marketed and action taken by the manufacturer and National Regulatory Authority concerned;
6. Site or plant master file as specified in Appendix I of the Fourth Schedule;
7. Constitution details of the firm [of domestic manufacturer or authorised agent];
8. Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the medical device;
9. Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the fifth schedule.

In the case of the Class B device, the device master file must also be provided in addition to other information. The site or plant master file must contain, *inter alia*, general information on the use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing, and a short description of the quality management system of the company. With regard to equipment, description is required as to the qualification and alliteration, including the recording system, and arrangements for computerised systems validation. The description of arrangements for the handling of complaints and for the handling of field safety corrective action is also required to be provided. All devices approved for sale in India must be accompanied by a Declaration of Conformity, including details of applicable safety directives the product complies with and details of relevant standards. A Design dossier that includes detailed information about the design,

function, composition, use, claims, and clinical evaluation of the device is also required for registration of a Class B device.

Product specification dossier with that must contain, *inter alia*, the intended population and medical condition, description of the accessories, configurations and variants, and its functionality. An explanation of any novel features is to be included. Labelled pictorial representations—diagrams photographs and drawings—clearly indicating key parts or components, including sufficient explanation to understand the drawings and diagrams, should be included. Performance attributes should also be included. The dossier should contain enough information to allow the reviewer to obtain a general understanding of the device.

The verification and validation of the medical device should include information covering

- a) Engineering tests;
- b) Laboratory tests;
- c) Simulated use testing;
- d) Any animal tests demonstrating feasibility of proof of concept of the finished device; and
- e) Any published literature regarding the device or substantially similar devices.

The summary information may include a declaration or certificate of conformity to a recognised standard and summary of the data if no acceptance criteria is specified in the standard. A declaration or certificate of conformity is to be provided to a professional guideline, industry method, or in-house test method, supported by a rationale for its use. Detailed biocompatibility study data as prescribed standards and software verification and validation should be provided in addition to clinical evidence.

Where there is no predicate device, additional data is to be provided, including mechanical and electrical tests, reliability tests, risk management data, proposed instructions for use, design input, and device specification, including specificity, sensitivity, reproducibility, and reputability. Design input means the physical and performance requirements of the device that are used as the basis for device design.

The product dossier must also contain the product specification—any requirement with which a product, process, service, or other activity to which the product must conform—and the methods

needed to identify the processes for quality management and how the processes may be monitored, measured, and analysed. The application form for regulatory approval from the device manufacturer should include description of the document management system. A documented procedure for design and development shall be set in place, and the process of control of design and development, as well as the processes of review, verification, validation, and design transfer, shall be included in the documentation submitted to the regulatory authority.

Clinical Investigation

Clinical investigation is covered under Para 2 of the Seventh Schedule of the Medical Devices Rules, 2017. Clinical investigation on an investigational medical device can only be initiated after approval has been obtained from a registered ethics committee⁴⁷. As of April 1, 2018, the Clinical Trials Registry–India, CTRI, accepts and registers trials only prospectively; therefore, investigators whose proposals have been approved by the ethics committee must register with the CTRI before the enrollment of the first participant.

The investigator should possess appropriate qualification, training, and experience, and should have access to such investigational and treatment facilities as are relevant to the proposed clinical investigation. A qualified physician who is a sub-investigator for the investigation shall be responsible for all investigation-related decisions concerning medical issues. Laboratories used for generating data for clinical investigation should be compliant with Good Laboratory Practices (GLP) or should have accreditation certificate issued by the National Accreditation Board for Testing and Calibration of Laboratories. According to Rule 58 of the Medical Device Rules, the sponsor and any other organisation or investigator shall disclose to the Medical Device Officer or any other officer authorised by the Central Licensing Authority the names, addresses and other particulars of persons involved in the clinical investigation. Any change of investigation plan should be implemented only after approval of the Ethics Committee and the Licensing Authority.

The sponsor is responsible for implementing and maintaining quality assurance system to ensure that the clinical investigation is designed, conducted, monitored and that the data is generated, documented, recorded, and reported in compliance with clinical investigational plan and Good Clinical Practices Guidelines issued by the CDSCO. The sponsor is also required to submit a status report on the Clinical Investigation to the Central Licensing Authority at the prescribed periodicity, including safety summary and deviations.

⁴⁷ Registered under rule 122DD of Drugs and Cosmetics Rules, 1945.

It is the duty of the sponsor to report any adverse event or serious adverse event to the Chairman of the Ethics Committee, Central Licensing Authority, and the head of the institution where the clinical investigation has been conducted within 14 days from the knowledge of the occurrence. In case of injury or death, the sponsor shall make payment for medical management of the subject and also provide financial compensation for clinical investigation related injury or death in the manner specified in the Drugs and Cosmetics Rules. The sponsor is also required to provide the clinical investigation report, whether for a completed or prematurely terminated investigation, to the Ethics Committee, participating investigators, and the Central Licensing Authority. In case the sponsor wishes to prematurely discontinue the investigation for want of commercial interest, he must inform the Central Licensing Authority and also submit a summary report within a period of ninety days having a description of the investigation, the number of patients exposed to the investigational medical device, details of adverse device affect or serious adverse event, compensation paid, if any, and the reason for discontinuation of the investigation or non-pursuit of the investigational medical device application.

The Investigator is responsible for the conduct of the investigation in accordance with his undertaking to adhere to

- clinical investigation plan
- GCP guidelines

Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in an investigation, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. The investigator shall report all serious adverse events to the Central Licensing Authority, sponsor, and the Ethics Committee within 48 hours of the occurrence. In case the investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reason for the delay to the Central Licensing Authority along with the report of the serious adverse event. The detailed report, after due analysis, shall be forwarded by the investigator to the Chairman of the Ethics Committee, the Central Licensing Authority, and the head of the institution where the investigation has been conducted, within fourteen days of occurrence.

The investigator shall provide information to the clinical investigation subject through informed consent process as provided in the Rules about the essential elements of the clinical investigation and the subject's right to claim compensation in case of investigation-related injury or death. He shall also inform the subject or his/her nominee of their rights to contact the sponsor or his representative for making claims in case of investigation-related injury or death.

It is the responsibility of the Ethics Committee to safeguard the rights, safety, and well-being of all study subjects. The committee should exercise particular care to protect the rights, safety, and well-being of all study subjects. The Ethics Committee should exercise particular care to protect the rights, safety, and well-being of all vulnerable subjects participating in the study. The vulnerable subject, according to the *explanation*, are members of a group with hierarchical structure, patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors and other persons incapable of personally giving consent. Ethics committees must have documented Standard Operating Procedures and should maintain a record of its proceedings. The committee should undertake ongoing review of approved projects based on periodic study progress reports furnished by investigators or monitoring and internal audit reports of the sponsor. In case an Ethics Committee revokes site approval, it shall record reasons for doing so and, at once, communicate such a decision to the investigator as well as to the Central Licensing Authority. Any report of serious adverse event, after due analysis, shall be forwarded by the Chairman of the Ethics Committee to the Central Licensing Authority and to the head of the institution where the clinical investigation has been conducted, within 14 days of the knowledge of occurrence of the serious adverse event.

Sub para 5 of Para 2 of the Seventh Scheduled covers Informed Consent. In all investigations, a freely given informed written consent is required to be obtained from each study subject. The investigator shall provide information about the study verbally and through the patient information sheet in a language that is non-technical and is understandable by the study subject. The subjects' consent must be obtained in writing using an 'Informed Consent Form'. The patient information sheet as well as the Informed Consent Form shall be approved by the Ethics Committee and furnished to the Central Licensing Authority. Any change in the informed consent documents should be approved by the Ethics Committee and submitted to the Central Licensing Authority before such changes are implemented.

Where a subject is not able to give informed consent, e.g. an unconscious person, or person suffering from severe mental illness or disability, the same may be obtained from a legally acceptable representative. If the subject or his legally acceptable representative is unable to read or write, an impartial witness should be present during the entire informed consent process who must append his signature to the consent form. A legally acceptable representative means a person who is able to give consent or authorise an intervention in the patient as provided by the law in India. The informed consent process, in case of vulnerable subjects in clinical investigations of an innovative medical device which is not approved anywhere in the world, shall be audio-video recorded.

Types of Investigation

The rules contemplate different types of investigation:

Pilot Clinical Investigation

A pilot clinical investigation is defined as those clinical investigations that are used to acquire specific essential information about a device before beginning the pivotal clinical investigation. It is an exploratory study that may be conducted on a few patients with the disease or condition being studied before moving on to a large population and scope that give insight into the performance and safety of a device but cannot provide definitive support for specific mechanistic or therapeutic claims. The objectives of the pilot clinical investigation, including assessing feasibility [preliminary device performance], exploring eligibility criteria, and a practical application for pivotal controlled investigation, ascertaining potential harm [preliminary safety evaluation], studying device mechanism, validated a method for determining and outcome measure using a defined device mechanism to validate a surrogate outcome measure and evaluating the logistics of pivotal investigation for performance.

Pivotal Clinical Investigation

The pivotal clinical investigation is the definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Pivotal clinical investigation is a confirmatory study that may be conducted on a large number of patients with disease or condition being studied and offers a scope to provide the effectiveness and adverse effects. For investigational Medical Devices that do not have a predicate medical device but have been approved for sale or distribution in any country other than India, pivotal studies need to be carried out primarily to generate evidence of safety and effectiveness of the medical device on

Indian patients when used as recommended in the prescribing information, except in the case of investigational medical device classified under Class A where pilot clinical investigation is required. Prior to conduct of pivotal clinical investigation on Indian subjects, the central licensing authority may require making the pilot study data available to assess whether the data is in conformity to the data already generated outside the country. If the application is for conduct of clinical investigation as part of a global clinical investigation of the medical device, the number of sites and patients as well as justification for undertaking such clinical investigation in India shall be provided to the central licensing authority.

Post-marketing Clinical Investigation

A Post-Marketing Clinical Investigation or Study is designed to identify the potential for residual risks of an approved device, and to collect data and gain clarity regarding the long-term clinical performance of product. Post-market investigation includes additional drug device interaction, safety studies, and investigation designed to support use under the approved indication [such as mortality or morbidity studies]. The licensing authority uses the post-marketing study data to gather additional information about the device's safety, efficacy, or optimal use. This investigation may not be considered necessary at the time of medical device approval but may be required by the central licensing authority for optimising the intended use of the medical device.

Studies in Special Populations

Clause 2(9) of the Seventh Schedule to the Rules enumerates the requirements to be complied with for studies in special populations, a class that includes children, pregnant women, nursing women, and elderly patients with renal or other organ system failure.

- Geriatric: Geriatric patients can be included in a pivotal study if the disease intended to be treated is characteristically a disease of aging or treats a condition commonly expected in the elderly, or if the population to be treated is known to be included in substantial numbers of geriatric patients.
- Paediatric: The timing of paediatric studies in the medical device development programme shall depend on the device, the type of disease being treated, safety consideration, and the safety and effectiveness of available treatment. The performance and safety study shall be made in the appropriate age group. It is usually appropriate to begin with older children before extending the investigation for younger children and then with infants.

Paediatric subjects less than 18 years of age are legally unable to provide written informed consent for participation in a clinical investigation. Parents or Legally Authorised Representatives (LAR) shall provide written informed consent for paediatric subjects below the age of 18. Paediatric subjects shall, nevertheless, be required to provide assent to participate in clinical investigations. Depending on the maturity of the individual concerned, a child as young as seven years may be asked to provide written assent, though written assent shall be required when the child is aged 12 and above. However, all paediatric patients shall be informed to the fullest possible extent about the study in a language and in terms that they are able to understand. Wherever appropriate, paediatric participants should additionally assent to enrol in the study. Mature minors and adolescents should personally sign and date a separately designed written consent form. Although a participant's wish to withdraw from the study shall be respected, there may be circumstances in which, in the opinions of the investigators and bearing or legal guardian, the welfare of the paediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent would be sufficient to allow participation in the study.

- **Pregnant or nursing women:** Pregnant or nursing women shall be included in the study only for Medical Devices intended for use by pregnant or nursing women or nursing infants. Pregnant or nursing women are only included in the trial if data generated from participation of women who are not pregnant or nursing would be unsuitable. For medical device intended for use during pregnancy, follow-up data pertaining to a period appropriate for that medical device on the pregnancy, foetus, and the child will be required.

Post-marketing Surveillance

Subsequent to approval of an investigational medical device, it shall be closely monitored for their clinical safety once they are marketed. The applicants must furnish Periodic Safety Update Reports (PSURs) for each device, in order to report all new and relevant information from appropriate sources, relate these to patient exposure, summarise the market authorisation status in different countries and any significant variations related to safety, and indicate whether changes will be made to product information in order to optimise the use of the product.

PSURs should be submitted every six months for the first two years, and for the subsequent two years, the PSURs need to be submitted annually. The Central Licensing Authority may extend the total duration for submission of PSURs if it is considered necessary in the interest of public health.

Investigator's Brochure and Clinical Investigation Plan

The investigator's brochure and the Clinical Investigation Plan has to be strictly adhered to by the investigator and co-investigators. Table 4 of the Seventh Schedule provides the details required to be submitted in the Investigator's Brochure. The Investigator's Brochure must contain detailed information on the device, including summary of literature and evaluation supporting the rationale for the design and intended use of investigational medical device. A general description of the investigational medical device and its components, including materials used, is to be provided. Relevant manufacturing processes and related validations process, along with the mechanism of action of investigational medical device and supporting scientific literature, is also to be provided. The brochure must contain the manufacturer's instructions for installation and use of the investigational medical device, including any necessary storage and handling requirements, preparation for use and any intended re-use, pre-use safety or performance checks and any precautions to be taken after use (e.g. disposal), if relevant. A description of the intended clinical performance is also to be provided.

In addition, data derived from preclinical testing, existing clinical data, and analysis of adverse device effects or history of modifications is also to be included. The investigator must include a summary of the risk analysis, including identification of residual risks, results of risk assessment and anticipated risks, contra-indications, warnings etc. for the investigational device. In addition, the investigator must provide a list of international standards, if any, complied with in full or part, a statement of conformity with national regulations, where appropriate, and a list of references, if relevant.

The clinical investigation plan is a document that contains an overview of the clinical investigation, including the design, such as inclusion or exclusion criteria, number of subjects, the duration of clinical investigation, expected duration of each subject's participation, follow-up, objective, and the end point. A justification for the design of the clinical investigation is to be provided, which must include an evaluation of the results of the relevant preclinical testing or assessment and an evaluation of the clinical data that are relevant to the proposed clinical investigation. Anticipated risks and benefits and possible interactions with concomitant medical treatments must be included. A risk-to-benefit rationale should also be provided. The plan must contain details of objectives and hypothesis of the clinical investigation in much detail. Primary and secondary objectives must be mentioned. Hypothesis, primary and secondary, to be accepted or rejected by statistical data from the clinical investigation must be included as well as, claims and intended performance of

investigational medical device that are to be verified. Risks and anticipated adverse device effects that are to be assessed must also be included. Comparators and any other medical device or medication to be used during the clinical investigation should be listed together with the justification for the number of investigational Medical Devices to be used.

A detailed description of all the clinical investigation-related procedures that subjects undergo during clinical investigation, and any known or foreseeable factors that may compromise the outcome of the clinical investigation or interpretation of results should be included. A clinical investigation plan shall also specify what medical care, if any, will be provided to the subject after the clinical investigation has been completed. A general outline of the monitoring plan to be followed, including access to source data and extent of source data verification planned shall be included. Statistical design, method, and analytical procedures, sample size, power of the investigation, expected drop-out rate, provision of interim analysis, treatment of missing, unused or spurious data, and exclusion of particular information from the testing of the hypothesis should be mentioned with justification. A description of the procedures for the accountability of investigational medical devices should be maintained.

Data management procedures, including database cleaning, data review, and resolving data queries, must be provided. Procedures for data retention, retention period, and aspects of clinical quality assurance should be included. Rule 57 of the Medical Device Rules requires that every sponsor, investigator, or Clinical Research Organisation shall maintain data, record, registers and other documents pertaining to the trial for a period of seven years after completion of such investigation, and shall furnish such information as may be required by the Central Licensing Authority. Any amendment to the clinical investigation plans should be as per procedures provided in the plan. Deviations from the plan should be recorded, reported, and analysed. The investigator must sign a statement undertaking that he is not allowed to deviate from the plan except with approval of the Ethics Committee and the Central Licensing Authority. Corrective and preventive actions must be provided for, including disqualification of the investigator on account of unauthorised deviation. The description of the informed consent process, including the process for providing subjects with new information as needed, is part of the plan. The plan may also include a statement indicating whether the results of the investigation would be submitted for publication, and the conditions under which the results of the clinical investigation will be offered for publication.

III. THE LEGAL ECOSYSTEM FOR RESEARCH

National and International Protections for Participants

At the end of the Second World War, German medical doctors were tried for performing medical experiments without subjects' consent on prisoners of war and civilians of occupied countries. In the course of these experiments, the doctors were accused of committing murders, brutalities, cruelties, tortures, atrocities, and other inhuman acts. They were also accused of planning and performing mass murder of prisoners of war and civilians of occupied countries, stigmatised as aged, insane, incurably ill, deformed, and so on, by gas, lethal injections, and diverse other means, besides participating in the mass murder of concentration camp inmates.

Out of the trial grew the first code of ethics in human experimentation. These were the 10 points of the Nuremberg Code:

1. Required the voluntary, well-informed, understanding consent of the human subject in full legal capacity.
2. The experiment should aim at positive results for society that cannot be procured in some other way.
3. It should be based on previous knowledge (e.g., an expectation derived from animal experiments) that justifies the experiment.
4. The experiment should be set up in a way that avoids unnecessary physical and mental suffering and injuries.
5. It should not be conducted when there is any reason to believe that it implies a risk of death or disabling injury.
6. The risks of the experiment should be in proportion to (that is, not exceeding) the expected humanitarian benefits.
7. Preparations and facilities must be provided that adequately protect the subjects against the experiment's risks.
8. The staff who conduct or take part in the experiment must be fully trained and scientifically qualified.

9. The human subjects must be free to immediately quit the experiment at any point when they feel physically or mentally unable to go on.
10. Likewise, the medical staff must stop the experiment at any point when they observe that continuation would be dangerous.

Although not legally guaranteed in any country of the world, the Nuremberg Code along with the Declaration of Helsinki (1964) and subsequent revisions of the Declaration have become an influential code governing medical practice and research ethics. The Declaration of Geneva (1948) is a statement of physicians' ethical duties during clinical research. Article 7 of the International Covenant on Civil and Political Rights specifically states: No one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

In 1993, the Council for International Organisations of Medical Sciences (CIOMS), an international NGO established jointly by the WHO and the UNESCO, promulgated the International Ethical Guidelines for Biomedical Research Involving Human Subjects. These guidelines have been updated several times, most recently in 2016.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996, defined a set of guidelines on the ethical aspects of clinical trials as well as for assuring scientific quality standards. These were the Good Clinical Practice (GCP) guidelines. The objective of the ICH GCP guideline was to provide a unified standard for the EU, Japan, and the U.S. to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

In addition to codes and guidelines, there is an emerging ecosystem of capacity building organisations and certifying organisations such as The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), a network of independently established regional fora for ethical review committees, health researchers, and invited partner organisations with an interest in the development of ethical review. SIDCER provides a voice for human subjects on research issues in national, regional, and international healthcare settings.

Based on international codes and guidelines, the Indian Council for Medical Research first brought out the 'Policy Statement on Ethical Considerations Involved in Research on Human Subjects' in

1980. The guidelines were revised in 2000 and 2006. In 2017, the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants was brought out to govern clinical trials in India. The guidelines worked on the original four basic principles:

1. **Non-Maleficence** — Non-maleficence means non-harming or inflicting the least harm possible to reach a beneficial outcome. Risk mitigation, protection from unreasonable levels of discomfort, and the necessity to prematurely terminate a trial that is demonstrating unacceptable levels of harm or adverse events are all part of the standard of non-maleficence.
2. **Autonomy** demands that the ability of competent subjects to make their own decisions be recognised and respected, while also protecting the autonomy of the vulnerable by preventing the imposition of unwanted decisions. Providing information to the participant of the trial on procedures, research harm, alternative and standard treatment, and benefit to the participant and community in sufficient detail and in a language/means accessible to the participant is an essential component of the exercise of autonomy.
3. **Beneficence** demands that subjects should not be harmed through the conduct of the study. Trial participants may benefit from the more rigorous standards for diagnostic and therapeutic procedures, quality control, drugs and devices not available outside the trial, greater attention from physicians, and easier appointments. However, it is also equally true that there is greater uncertainty in outcomes that the participant is subjected to when compared with a patient undergoing standard treatment. Beneficence also requires the highest standards of scientific integrity and validity. Any unplanned violation or protocol deviation carries the risk of jeopardising the safety of the patient, the validity of the results, and the nullifying of the consent already granted.
4. **Justice** demands the fair selection of research participation. The ideal distribution of research risks and benefits is assured when the investigator determines the inclusion criteria. The inclusion criteria should be based on scientific objectives, not membership of either a privileged or vulnerable population, in order to most equitably share the risks and benefits of the research.

The 2017 guidelines expanded the four basic principles into the following 12 general principles:

1. **Principle of essentiality** whereby, after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research. This should be duly vetted by an ethics committee (EC) independent of the proposed research.
2. **Principle of voluntariness** whereby respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are safeguarded.
3. **Principle of non-exploitation** whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured.
4. **Principle of social responsibility** whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.
5. **Principle of ensuring privacy and confidentiality** whereby, to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorised. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.), privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.
6. **Principle of risk minimization** whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimised and appropriate care and compensation is given if any harm occurs.
7. **Principle of professional competence** whereby the research is planned, conducted, evaluated, and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.
8. **Principle of maximisation of benefit** whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximise the benefits to the research participants and/or to the society.
9. **Principle of institutional arrangements** whereby institutions where the research is being conducted have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.

10. **Principle of transparency and accountability** whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports, and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/audit.
11. **Principle of totality of responsibility** whereby all stakeholders involved in research are responsible for their actions. The professional, social, and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders, directly or indirectly.
12. **Principle of environmental protection** whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research in compliance with existing guidelines and regulations.

Under Responsibility of Researchers, the guidelines specify that

In case of differently abled participants, such as individuals with physical, neurological, or mental disabilities, appropriate methods should be used to enhance the participants' understanding, for example, braille for the visually impaired.

The Guidelines define vulnerable persons as those 'who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens, social injustice, lack of power, understanding or ability to communicate, or are in a situation that prevents them from doing so'. Vulnerable groups and individuals may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) protecting their own interests. Vulnerable populations include persons or groups afflicted with mental illness and cognitively impaired individuals, different abled – mentally and physically disabled. In general, vulnerable participants should be included in research only when the research is directly answering the health needs or requirements of the group. On the other hand, vulnerable populations also have an equal right to be included in research so that benefits accruing from the research apply to them as well. It is the responsibility of the Ethics Committee to determine vulnerability and ensure that additional safeguards and monitoring mechanism are established. The Ethics Committees should also advice the researcher in this regard.

Additionally, the Guidelines expand on the concept of community engagement, which, under certain circumstances, apply to the disability sector. Community is defined as a social group of people of any size sharing the same culture, beliefs or gender, and also the same lifestyle, disease etc. The community should be meaningfully engaged before, during, and after the research to mitigate culturally sensitive issues and ensure greater responsiveness to their health needs and requirements. Members of the community can also be represented in the Ethics Committee either as members or special invitees. After the study is completed, the researcher may communicate with the community representative, local institution, or the government department from where the data was collected to help in dissemination of the results to the entire community. The benefits accruing from the research should be made accessible to individuals, communities, and populations whenever relevant. Post-research access arrangements or other care must be described in the protocol and subject to review by the Ethics Committee. The Guidelines require that the protocol disclose the participation of vulnerable groups and any mechanisms to protect them, including compensation, insurance, and post-research access.

The principles of research among vulnerable populations stated in Section 6.1 include, *inter alia*:

6.1.2 If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.

6.1.3 Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

6.1.4 In vulnerable populations, when potential participants lack the ability to consent, an LAR (Legally Acceptable Representative) should be involved in decision making.

6.1.5 Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

6.1.6 If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety, and well-being of these individuals.

It must be borne in mind that the International Classification of Functioning, Disability, and Health (ICF) defines disability as an umbrella term for impairments, activity limitations, and participation restrictions. Disability is the interaction between individuals with a health condition and persona and environmental factors such as negative attitudes and inaccessible transportation and public buildings. While some health conditions result in poor health and extensive health care needs,

others do not. In general, persons with disabilities have the same general health care needs as everyone else; however, they have greater unmet needs. Health promotion and prevention activities rarely reach people with disabilities – for instance, women with disabilities receive less screening for breast and cervical cancer than women without disabilities; people with intellectual impairments and diabetes are less likely to have their weight checked⁴⁸. As a consequence, persons with disabilities are likely to develop secondary, preventable conditions, and co-morbid conditions. Their health needs being different and also higher, researchers and ethics committees must ensure particular care towards these aspects. Whenever possible, ancillary care may be provided, such as setting up of a facility, school for unattended children of participants, or a hospital, or a counselling centre, as per 6.2.13.

Other additional safeguards must ensure that participants with disability do not feel exploited, rewarded, intimidated or pressured to participate. Researchers must justify the inclusion of persons with disability and the Ethics Committee must satisfy themselves with the justification provided and record the same. Vulnerable populations may suffer from more than one form of vulnerability such as gender and impairment, or social or economic background combined with impairment. In such cases, special safeguards are required, such as more frequent review and monitoring, including site visits. Ethics Committees should have Standard Operating Procedures (SOP) for handling proposals involving vulnerable populations.

Where children with disabilities are to be participants, such as children with cerebral palsy, it is the duty of the Ethics Committee, under Section 6.5 of the Guidelines, to determine whether consent of one or both parents would be required before the child can be enrolled. Where the research involves no more than minimal risk or offers direct benefits to the child, consent of one parent or LAR must be sufficient. Consent of one parent is acceptable if the other is deceased, unknown, incompetent, or when only the consenting parent has legal responsibility for the care and custody of the child. The consent form should include details specifically relevant to the child, such as effects on growth and development, psychological well-being, and school attendance, in addition to other components related to the conduct of the trial. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. Their parents are also considered vulnerable and there is a high likelihood of therapeutic misconception. In such cases, the benefits and risks must be carefully explained. Research involving institutionalised children

⁴⁸ **World Health Organization. 2018.** “[Factsheet: Disability and Health](http://www.who.int/news-room/fact-sheets/detail/disability-and-health)”, January 16. [http://www.who.int/news-room/fact-sheets/detail/disability-and-health].

must include permission of relevant institutional authorities, in addition to the consent of parent/s/LAR and assent of the child.

The Juvenile Justice (Care and Protection of Children) Act, 2015 defines ‘child-friendly’ as any behaviour, conduct, practice, process, attitude, environment, or treatment that is humane, considerate and in the best interest of the child. Read with the Guidelines, this Act requires the researcher and the site to be child-friendly. Again, ‘best interest of the child’ means the basis for any decision taken regarding the child to ensure fulfilment of his basic rights and needs, identity, social well-being, and physical, emotional, and intellectual development. Parents and LAR must be aware that wilfully exposing children to assault, abuse, or cruelty is punishable with imprisonment and/or fine⁴⁹. Therefore, it is also the duty of the parents/LAR to assess the benefits, risks, and best interest of the child when consenting to the participation of a child with disability. Researchers must ensure friendly people, fun activities and an age-appropriate child-friendly environment on site. Young children must have access to things that interest and motivate them, such as toys, encouragement, and kid-sized furniture to ensure that their participation provides a positive experience. Older children may be motivated with incentives that would encourage participation, including money or money substitutes such as gift cards or coupons⁵⁰.

The content of the assent form has to be in accordance with the developmental level and maturity of the child to be enrolled. The language must be consistent with the cognitive, social, and emotional status of the child; it must be simple and appropriate to the age of the child and must include an explanation of the study, a description of any discomfort the child is likely to feel, and contact information of the person whom the child can approach for further explanation. The child should know that she can refuse to participate. There is no need to document assent for children below the age of seven; however, their assent must be assessed and non-cooperation must be respected at every visit or intervention. For children between seven and 12 years of age, verbal/oral assent must be obtained in the presence of parent/LAR and should be recorded. For children between the ages of 12 and 18, written assent is required duly signed by the parent/LAR.

Where participants with mental illness are to be involved, the researcher must inform the participant as well as the Ethics Committee how the research will address a participant’s suicidal

⁴⁹ Section 75

⁵⁰ Greenberg, R. G. et al. 2018. ‘[Parents' perceived obstacles to pediatric clinical trial participation: Findings from the clinical trials transformation initiative](https://www.sciencedirect.com/science/article/pii/S2451865417301564)’, Contemporary Clinical Trials Communications: *Elsevier B.V.*, March, Vol. 9, Pg. 33-39. [<https://www.sciencedirect.com/science/article/pii/S2451865417301564>].

ideation or other risk of harm to themselves or others. The participant must be informed that their confidentiality may be breached for reporting to family member, police, or other authorities, or they may have to be admitted to hospital upon expression of such thoughts. Interventions should be of short duration and in accordance with relevant laws.

Questions may be raised as to whether guidelines are advisory or mandatory and what regulatory functions they serve. While Schedule Y of the Drugs and Cosmetics Act, 1945, is mandatory, clarity is required regarding the relationship between the legislation and the guidelines. In the realm of Clinical Trials, the ICMR guidelines are treated as mandatory unless there are reasonable grounds for departure. Other guidelines are only advisory, though courts are required to at least consider them. In the evolving ecosystem, many ethical considerations originally found in the guidelines are being encoded in legislation. In 2016, a draft bill to regulate clinical trials of drugs was tabled before the Lok Sabha but was not passed.

Be that as it may, it is important to note that failure to comply with specific provisions of Drugs and Cosmetics Act, 1945, its schedules or rules framed pursuant to the Act, may result in adverse criminal consequences.

The Rights of Persons with Disabilities Act

The Rights of Persons with Disabilities Act, 2016 is a game changer law for a number of reasons, including the inclusion of several new categories of disabilities and for enabling employment of persons with disabilities in the private sector. This Act was found to be very useful in the current study as there are several aspects of research and challenges for the sector in respect of access to assistive devices and rehabilitation devices which are addressed.

Section 6(1) states that the appropriate government (state or centre) shall take measures to protect persons with disabilities from being subjected to torture or cruel, inhuman, or degrading treatment. Sub-section (2) of Section 6 goes on to state that no person with disability shall be a subject of any research without his or her free and informed consent obtained through accessible modes, means, and formats of communication; and prior permission of a Committee for Research on Disability constituted in the prescribed manner for the purpose by the appropriate government in which not less than half of the members shall themselves be either persons with disabilities or members of a registered organisation. This section must be read with Section 96 of the Act which states that the provisions of the Rights of Persons with Disabilities Act is in addition to, and not in derogation

of, the provisions of any other law for the time being in force. This means that the provisions of the Drugs and Cosmetics Act, the schedules thereof, and the rules framed under the Act are also to be taken into consideration.

It is significant that the prohibition against subjecting persons with disability to research, except with their free and informed consent, and prior permission of the Committee for Research on Disability, is a sub-section in a provision dealing with measures to protect such persons from being subjected to torture or cruel, inhuman, or degrading treatment. It is evident that failure to obtain free and informed consent and prior permission would amount to torture and cruelty. This demonstrates an awareness on the part of Parliament that persons with disability are vulnerable to deprivation of statutory safeguards during research. It is to be noted that the Legislature makes a distinction between research-related harm to participants with disability *vis-à-vis* other forms of abuse, violence and exploitation dealt with under Section 7.

Section 28 of the Act requires the appropriate government to initiate or cause to be initiated research and development through individuals and institutions on issues which shall enhance habilitation and rehabilitation and on such other issues which are necessary for the empowerment of persons with disabilities. The section requires the appropriate government to respond to the challenges being faced by persons with disabilities through the setting of research priorities. Research priority setting can be understood as an activity to decide which unmet needs are most urgent and can be best met through research. The exercise should be initiated, designed, and implemented in a specific context, setting and population with specific principles, values and preferences.

The Act clearly comprehends the need for universal design of consumer products and products of daily use. Section 41(2) requires that the

- a. 'appropriate government to develop schemes programmes to promote the personal mobility of persons with disabilities at affordable cost to provide for
- b. retrofitting of vehicles and
- c. personal mobility assistance.'

Section 2(ze) of the Act defines universal design as design of products, environments, programmes and services to be usable by all people to the greatest extent possible without the need for

adaptation or specialised design and shall apply to assistive devices including advance technologies for particular group of persons with disabilities. Section 42 requires the government to ensure that

‘(iii) electronic goods and equipment which are meant for everyday use are available in universal design.’

Section 43 requires the appropriate government ‘to take measures to promote development, production and distribution of universally designed consumer products and accessories for general use for persons with disabilities’.

Offences under the Act are covered in Chapter XVI. Section 89 states that any person who contravenes any of the provisions of this Act, or of any rule made thereunder shall for first contravention be punishable with fine which may extend to INR 10,000 and for any subsequent contravention with fine which shall not be less than INR 50,000 but which may extend to INR 500,000. Where an offence has been committed by a company, Section 90 states that every person who at the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly. A company under the Act includes any body corporate, including a firm or other association of individuals.

Further, Section 95 adds: Where an act or omission constitutes an offence punishable under this Act and also under any other Central or State Act, then, notwithstanding anything contained in any other law for the time being in force, the offender found guilty of such offence shall be liable to punishment only under such Act as provides for punishment which is greater in degree. The Central Government Rights of Persons with Disabilities Rules, 2017 came into effect on the April 22, 2017. The Rules contemplate a Central Committee for Research on Disability. Rule 5 states that no person with disability shall be a subject of research except when the research involves physical impact on his body. The Tamil Nadu State Rights of Persons with Disabilities Rules (Draft), 2018 have not come into effect, but also provide for a Committee for Research on Disability.

Aligning Ethical Standards with Legal Standards

Constitutional standing: Article 21 guaranteeing protection of life and liberty except according to procedure established by law has been expanded to include privacy and decisional autonomy. The informed consent process is the main component of decisional autonomy. Decisional autonomy is the freedom available to a potential participant whether to participate in the trial or not. For a participant to decide whether or not to participate, s/he should be provided with sufficient information in the language and means accessible to her or him. Having received the information, the participant should have the privacy and freedom to come to a decision. The potential participant should also be free to discuss the trial and the information with persons whose opinions s/he values. In *K.S. Puttaswamy v. Union of India* [(2014) 6 SCC 433], the Supreme Court explored the concept of Decisional Autonomy within the concept of privacy, stating that

*the dignity of the individual encompasses the right of the individual to develop to the full extent of his potential.
And this development can only be if an individual has autonomy over fundamental personal choices.*

The ability and freedom of the participants to make informed choices for themselves may be constrained by educational or social backwardness, social structures that do not enable individuals to exercise decisional autonomy and other barriers such as language and physical or cognitive impairments. Informed consent may also be defeated through inducement, insufficient information, and persuasion by persons having influence over the potential participant.

Criminal liabilities: Section 88 of the Indian Penal Code (IPC) provides an exemption from punishment for an *Act not intended to cause death, done by consent in good faith for person's benefit*. The section reads that an act is not an offence by reason of any harm caused by it, even if the doer is aware that it may cause the harm, if it is done with the consent of the person to whom harm has been caused; the latter person should have given consent to suffer that harm, or to take the risk of that harm. Section 89 provides that an act which is done for the benefit of a child, by consent of the guardian is not an offence by reason of any harm it may cause.

These provisions protect surgeons who perform surgeries with consent in the event of potential harm to the patient. However, in the case of a guardian consenting on behalf of a child or person of unsound mind, the exception shall not extend to the doing of an act likely to cause death, for any purpose other than the preventing of death or grievous hurt, or the curing of any grievous

disease or infirmity. Informed consent implies that the giver of consent is fully aware of the consequences of the procedure he or his ward is to undergo.

As per Section 90 of the IPC, a consent is not consent if it is given by a person...under a misconception of fact, and if the person doing the act knows or has reason to believe that the consent was given in consequence of such misconception. The clinical investigator must thus be aware of the risks of poor compliance with informed consent requirements. Failure to adhere to consent processes may result in criminal prosecution of the investigator for culpable homicide not amounting to murder (section 304) or voluntarily causing hurt under Section 321.

Any deviation from the approved investigational plan and procedures has the effect of nullifying the informed consent granted by the participant. Informed consent is a continuous process that is initiated at the signing of the consent form and terminated at the conclusion of the trial. Any approved deviations require a re-consent process. At the nullification of the consent, the researcher is liable for professional negligence, as if he had never procured consent. Section 304A of the IPC provides for punishment for causing death by negligence, while section 338 deals with rash and negligent act leading to grievous hurt.

The investigators in a clinical trial In *Jacob Mathew V. State of Punjab and Another* (Supreme Court, 2005), the court examined the concept of professional negligence, and as to when and how it does give rise to an action under criminal law. Actionable negligence according to the decision involves three constituents —

- (1) a legal duty to exercise due care on the part of the party complained of towards the party complaining the former's conduct within the scope of the duty,
- (2) breach of the said duty, and
- (3) consequential damage.

An investigator who is a medical professional, therefore, owes his subject a dual duty of care — one as a medical professional and the other as a researcher. In the law of negligence, professionals such as lawyers, doctors, architects and other are included in the category of persons professing some special skill or skilled persons generally. Persons dealing with professionals are assured that the skills possessed by the professional shall be exercised with professional competence and exercised with reasonable degree of care and caution.

Vulnerable populations: In addition to the protections provided for in the ICMR Guidelines, Schedule Y of the Drugs and Cosmetics Act in Responsibilities of the Ethics Committees, provides definition of vulnerable populations to include prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions.

In India, members of gender, caste, class, and ethnic identity experience structure of discrimination that impact their health, well-being and access to health care. The Scheduled Castes and the Scheduled Tribes [Prevention of Atrocities] Act, 1989, provides special protection to persons belonging to Scheduled Castes and Scheduled Tribes. Section 3(v) of the Act states that any offense against a person or property committed under the IPC on the ground that such person is a member of a Scheduled Caste and Scheduled Tribe shall be punishable with imprisonment for life and with fine. Persons with disability recruited as participants may belong additionally to a socially or educationally backward class. This means that their impairment and the social disability faced by them must both be adequately addressed in a trial involving persons with disability.

When including persons who are suspected to live in violent households, investigators must consider compromised decision-making capacities and emotional burden. A large proportion of women in India suffer from reduced autonomy and domestic violence. Domestic violence is also indicative of disempowerment and loss of autonomy. In general, women in traditional patriarchal societies in India do not benefit from financial autonomy, have restricted freedom of movement, and minor participation in household decision-making⁵¹. The term domestic violence in the Protection of Women from Domestic Violence Act, 2005, includes economic and emotional abuse. The term vulnerable population, therefore, must be extended to those being inhibited by structural social hierarchy as well.

The Maintenance and Welfare of Parents and Senior Citizens Act, 2007 casts an obligation on children and relatives of senior citizens to maintain such person and provide such necessities as may enable the senior citizen to lead a normal life. The Act defines maintenance as including provision for food, clothing, residence and medical attendance and treatment. Welfare includes health care, recreation centres and other necessary amenities for senior citizens. Elderly persons are, owing to their age, susceptible to diseases and health conditions. They may suffer physical and cognitive impairments and general disempowerment in the social sphere. Like other forms of

⁵¹ Sabarwal, S. et al. 2014. "Women's autonomy and experience of physical violence within marriage in rural India", *Journal of Interpersonal Violence*, Vol. 29, Issue. 2, pg. 332-347.

family violence and domestic abuse, elder abuse has developed into a public health and criminal justice concern. Besides physical abuse and neglect, elders also face infantilization, overprotection and loss of autonomy within the household. Financial abuse—extortion and control of pensions, theft of property, and exploitation in other ways—also reduces their ability to control their lives and personhood. Researchers recruiting senior citizens with disabilities must be cognizant of any ‘elder abuse’ in their homes or in residential or other institutional settings. Where research involves persons with disabilities, the principal investigators, researchers, Ethics Committees, institutions, and sites must be cognizant and fully comprehend the rights of persons with disabilities, and the various facets of their vulnerability—independently and in combination with socio-economic factors, age and gender.

IV. ANALYSIS OF GAPS IN ETHICAL CONDUCT OF RESEARCH

A 2012 WHO paper advocates the use of data from registered clinical trials to identify gaps in health research and development⁵². The authors surmise that databases of registered clinical trials may offer a new source for gaining insight into the health R&D landscape. As trial registrations become mandatory and accepted as an ethical and scientific responsibility, these registries will evolve into repositories of important data on disease condition and R&D focus and spending. Registered trials contain information that is complementary to published articles and their standardised and searchable format make it suitable for aggregate analysis.

The World Medical Association, Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, requires in Clause 35 that “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject”. Further, researchers have a duty to make publicly available the results of research and are accountable for the completeness and accuracy of their reports. The WHO considers the registration of trials a scientific, ethical, and moral responsibility, on the ground that it helps persons to make informed health care decisions based on all available evidence. Awareness of similar or identical trials will make it possible for researchers and funding agencies to avoid duplication and enable collaboration. The description of trial procedures and progress makes it easier to identify gaps in the research and registration may facilitate recruitment of appropriate participants. Further, registry data would help prospective meta-analysis, and registries checking data as part of the registration process may lead to improvements in the quality of clinical trials by making it possible to identify potential problems early in the research process⁵³.

Currently, the Drugs and Cosmetics Act, 1945 requires mandatory registration of the clinical trials in the Clinical Trial Registry of India. Further, those investigators looking for peer-reviewed publications in respected journals should register their trials. The International Committee of Medical Journal Editors (ICMJE) policy on clinical trial registration requires ICMJE journals to only consider those trials that are registered. The policy requires prospective registration of all

⁵² Viergever, R. F. et al. 2013. “[Use of data from registered clinical trials to identify gaps in health research and development](http://www.who.int/bulletin/volumes/91/6/12-114454.pdf)”, *Bull World Health Organ*, Vol. 91, Pg. 416–425C. [http://www.who.int/bulletin/volumes/91/6/12-114454.pdf].

⁵³ *World Health Organization*. “[Trial Registration](http://www.who.int/ictrp/trial_reg/en/)”. [http://www.who.int/ictrp/trial_reg/en/].

clinical trials, including interventions and devices. Registries the WHO designates as primary registries will be acceptable to the ICMJE. Currently, registration in English and native language of the registry are acceptable to meet the ICMJE's registration policy.

The Clinical Trial Registry of India (CTRI) hosted at the ICMR National Institute of Medical Statistics is a free and online public records system for registration of clinical trials being conducted in India that was launched on July 20, 2007. Initiated as a voluntary measure since June 15, 2009, trial registration in the CTRI has been made mandatory by the Drug Controller General, India. As of April 1, 2018, in compliance with the Helsinki Declaration, no trial can be registered after recruitment of the first participant. Moreover, editors of biomedical journals of 11 major journals of India declared that only registered trials would be considered for publication. Today, any trial involving human participants of any intervention, such as drugs, surgical procedures, preventing measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH, is expected to be registered in the CTRI before enrolment of the first participant.

Trial registration in CTRI⁵⁴ requires the Investigator and Sponsor to provide the following details—

1. Public title of the study (A title intended for the lay public in easily understood language)
2. Scientific title as it appears on the protocol, including trial acronym, if any
3. Secondary ID such as protocol number or any other trial registry number
4. Principal Investigator's name and address and contact for local person; in the case of a postgraduate thesis, the guide should concerned account as the PI while registering
5. Contact persons for scientific query, who may be the same as the PI
6. Contact person for public query who will respond to general queries, including information about current recruitment status, who may be the same person as the contact person for scientific query
7. Sources of monetary funding
8. Name and address of primary sponsor; in case of investigator-initiated trials, the institution may be acknowledged as the source of funding
9. Name and address of secondary sponsor
10. Countries of recruitment

⁵⁴ **Clinical Trial Registry – India. 2011. “CTRI Dataset and Description”,** January 1. [http://ctri.nic.in/Clinicaltrials/CTRI_Dataset_and_Description.pdf].

11. Sites of study
12. Name of Institutional Ethics Committee and approval status
13. Regulatory clearance status
14. Health condition and/or problem studied
15. Study type
16. Intervention and comparator agent
17. Inclusion/Exclusion criteria
18. Method of generating randomisation sequence
19. Method of allocational concealment
20. Blinding/masking
21. Primary outcomes
22. Secondary outcomes
23. Target sample size
24. Phase of Trial
25. Date of first enrolment
26. Estimated duration of trial
27. Recruitment status of trial
28. Brief Summary

After registration of the trial, the Investigator is expected to regularly update trial status or other aspects as the case may be. Once the trial is registered, all updates and changes will be recorded and available for public display. Guidelines and clarifications have been issued to help smoothen submission. Gaps remain in the registration process that need to be addressed with speed to improve both accessibility as well as quality of the trial. For instance, in several clinical trials, the only point of contact provided is the principal investigator. The explanation provided in the public query column that it could be the same person as the person responding to the scientific query, who could be the same person as the principle investigator reduces the means by which a concerned member of the public or a participant could reach a responsible party other than the principle investigator. This also means that if the principle investigator is not in a position to respond to queries, queries will remain unattended. There are only two genders provided for, which means that persons who are transgender or gender non-conforming cannot participate in potentially beneficial studies. In some studies, inclusion and exclusion criteria are inconsistent with responsible outcomes, for instance, the public title of the study being *'a clinical trial to study the effect*

of psychological treatment on the mothers explanations about the cause of intellectual disability in children and adolescents,' the inclusion criteria is specified as

Age from: 2 years to 18 years

Gender: both

Evidently, the inclusion criteria would be mothers with children in the age group 2 to 18 years. In general, a clinical trial registry staff member will review the study record after it is submitted and before it is published. The review focusses on apparent validity, meaningful entries, logic and internal consistency, and formatting. Investigators may be asked to clarify items or make

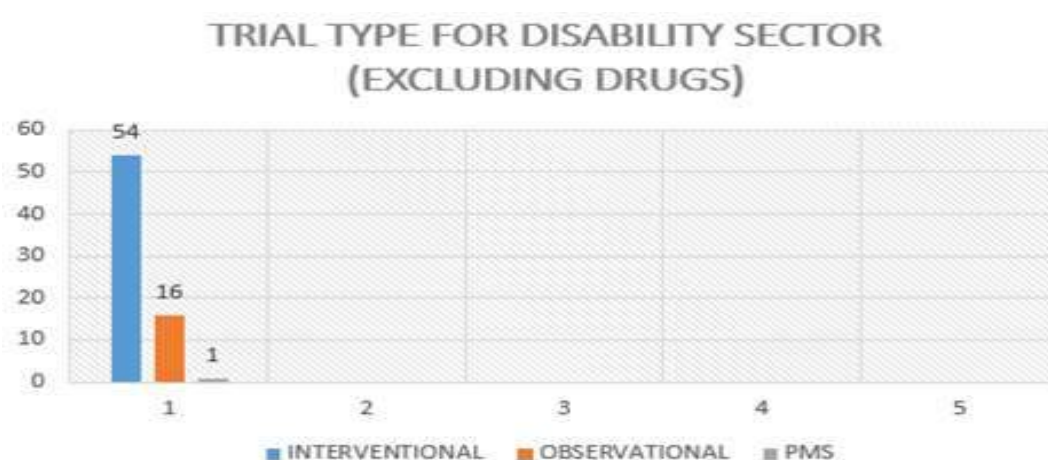


Chart 1: Disability-related Trials in India

Source: Compiled by Author using data from <http://ctri.nic.in/Clinicaltrials/pubview.php>

corrections to the record before publication. However, the review does not go into the validity of the research, research design, or protocol. Additional updates must be submitted within the required period (15 days or 30 days) and responsible parties (sponsors or investigators) must submit the summary results after primary completion date, defined as the date the final participant was examined or received intervention for purposes of final collection of data for the primary outcome.

As the database was of manageable size, this Report did not to use a sample of the registered trials. This study found that there is little correlation between the burden of disability and the R&D effort to address specific disabilities. In one per cent of the 14,152 (as on May 26, 2018) registered trials inclusion criteria included persons with disability; of these, 80 trials involving persons with disability did not use any drugs. These 80 trials were selected to study the gaps in ethical conduct since they would be impacted less by medical decisions based on daily review. The registered record of the trial was the only source of information. No additional research was done on the

record. Out of the total number of trials registered with CTRI, approximately one per cent of the trials involve persons with disability. These trials involve interventions, including therapy, device trials, and drugs.

The classification is based on data provided by the Investigator/sponsor on the CTRI database. Interventional studies are a type of study where participants are assigned to groups that receive one or more intervention/treatment. In some cases, the comparator group may not receive any treatment, in order to evaluate the effects of the interventions on health-related outcomes. Observational studies draw inferences from a sample to a population where the independent variable is not under the control of the researcher because of ethical concerns or logistical constraints. Only one post-marketing surveillance (PMS) study was found in respect of devices. A post-marketing surveillance is a study to monitor the safety of a device after it has been released in the market. PMS enables the manufacturer to further refine or confirm the safety of a drug or device after it has been used in the general population by large numbers of people with a wide variety of medical conditions.

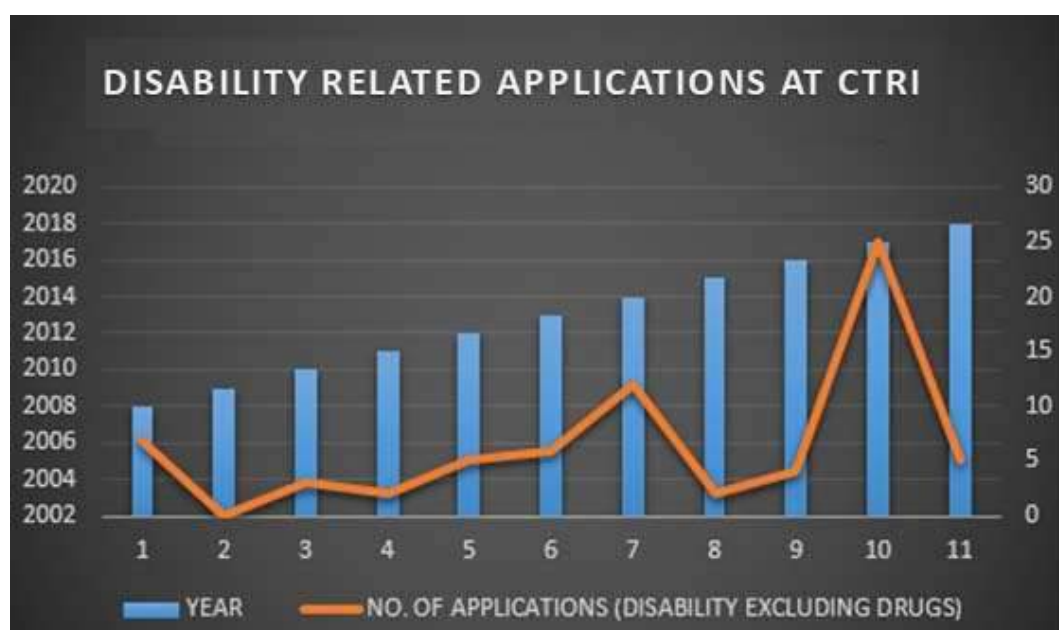


Chart 2: Year-wise data on no. of Disability-related Trials

Source: Compiled by Author using data from <http://ctri.nic.in/Clinicaltrials/pubview.php>

The CTRI records show that there have been trials of participants with disabilities in trials of various types since 2008. These include observational studies, drug trials, drug equivalence studies, device trials and device equivalence studies. There is also a rising trend in device trials, both equivalence and new devices, involving participants with disabilities. With the new ecosystem constraining involvement of persons with disabilities, it remains to be seen whether this trend would continue. Researchers and sponsors may also have to wait until the setting up of the Committee for Research on Disability to get prior permission to involve participants with disabilities.

The predominant disabilities represented are cerebral palsy, mental retardation, hearing and vision impairment, Parkinson's disease and locomotor disorders. Involvement of persons with depression and mental illness are found in observational studies and drug trials. Conditions of elderly resulting in significant disability were also taken into consideration.

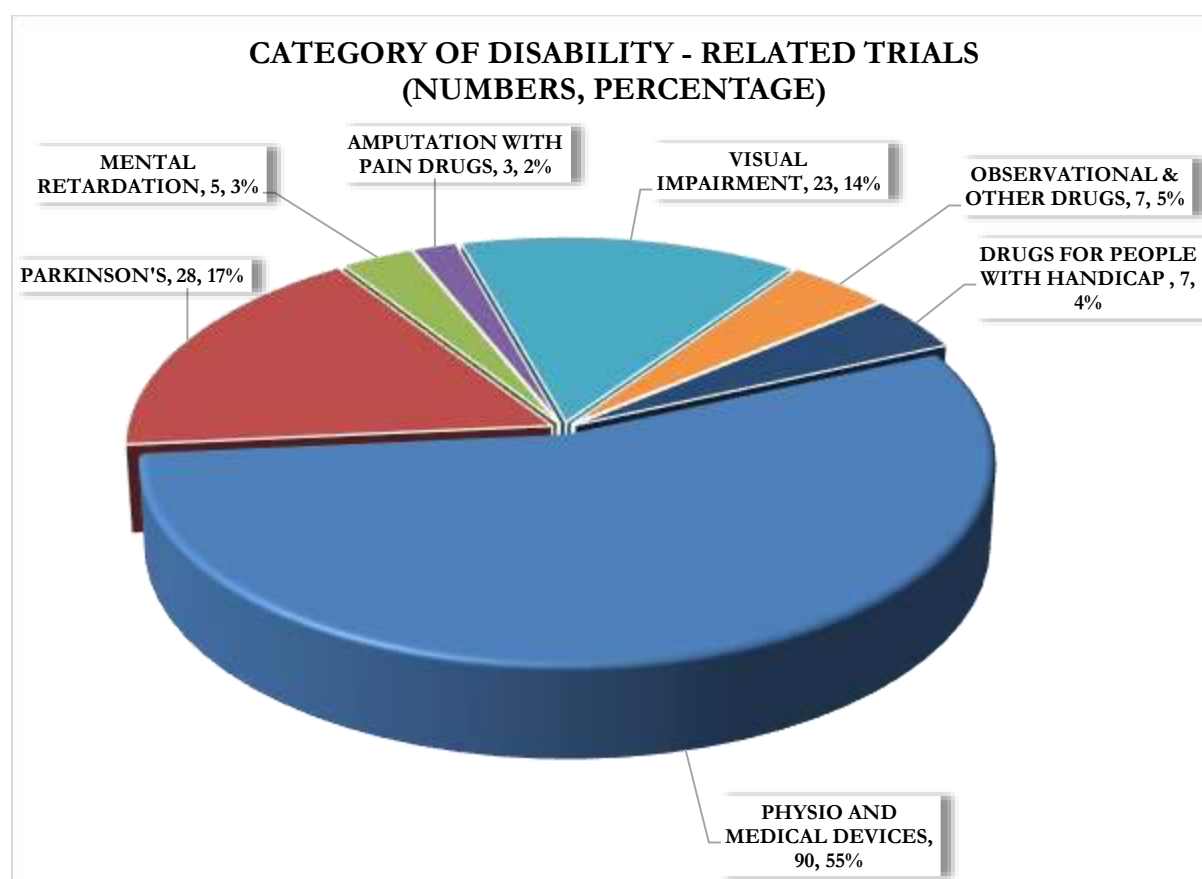


Chart 3: Categories of Disability-related Trials

Source: Compiled by Author using data from <http://ctri.nic.in/Clinicaltrials/pubview.php>

Among the 80 trials selected for the study, the following disabilities were represented:

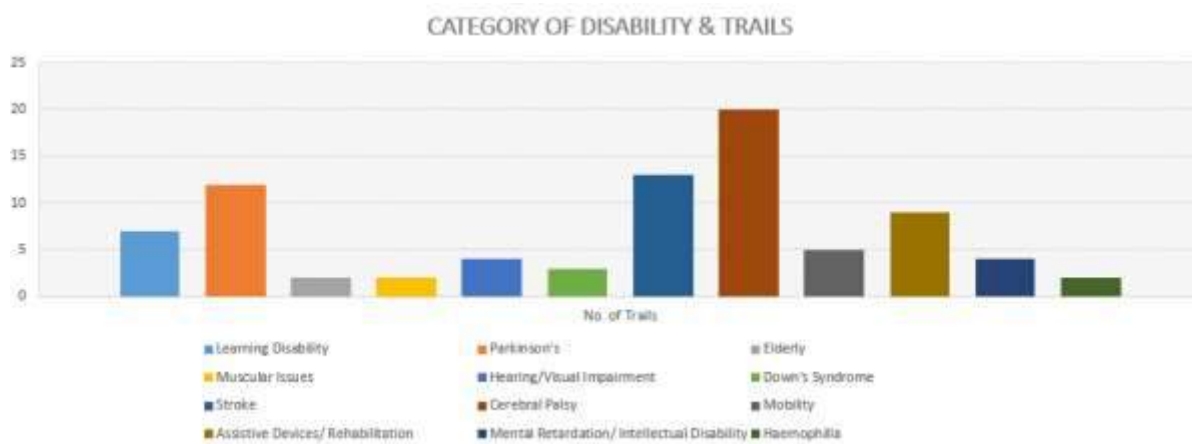


Chart 4: Categories of disability to which trials related

Source: Compiled by Author using data from <http://ctri.nic.in/Clinicaltrials/pubview.php>

Only nine studies pertained to disabilities resulting from traumatic injuries, amputations, and spinal injuries. A total of 25 studies took place in an institutional setting including rehabilitation centres and non-medical institutions of higher education. 5 trials related to technologies developed in non-medical institutions including IITs.

State Wise Statistics On Disability Category Trials (Excluding Drugs) at CTRI	
STATE	No. Of Trails In Disability Category (Excluding Drugs)
Andhra Pradesh	2
Delhi	6
Gujarat	3
Haryana	2
Karnataka	21
Kerala	1
Maharashtra	10
Manipal	1
Meghalaya	1
Punjab	3
Tamil Nadu	14
Uttar Pradesh	2
West Bengal	5

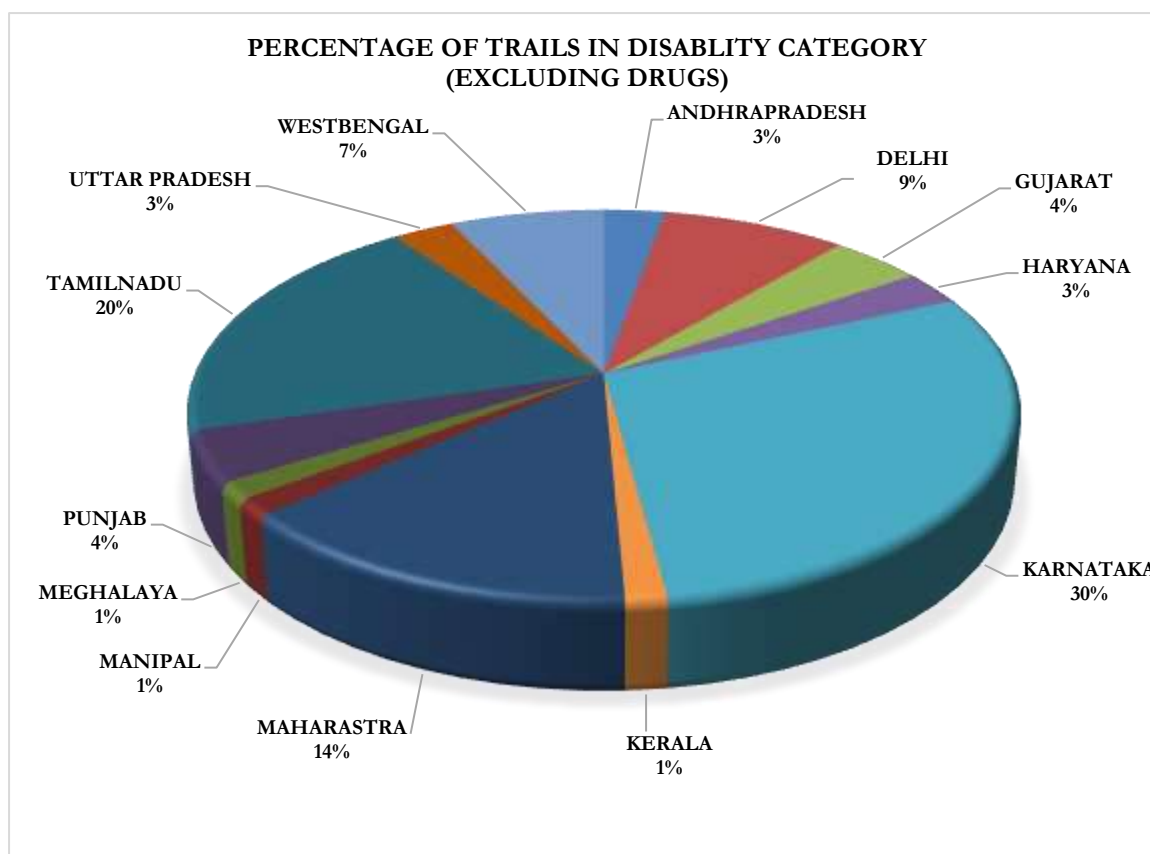


Chart 5: Categories of Disability to which trials related
Source: Compiled by Author using data from <http://ctri.nic.in/Clinicaltrials/pubview.php>

The largest number of device trials involving participants with disabilities took place in Karnataka (21), followed by Tamil Nadu (14) and Maharashtra (10).

A detailed analysis was conducted on the different input in each registry record. Based on the data in the record, every record was studied for completeness of information, and any non-compliance or partial non-compliance of regulatory law or the ICMR guidelines. The factors studied were type of trial, nature of trial, whether informed consent formalities are mentioned, appropriateness of inclusion exclusion criteria, safety monitoring as represented by adequate information of stakeholders and person to be contacted for public query, standards of device or intervention, appropriate qualification and competence of investigators, data analysis method, and whether risk management and data management policy are mentioned. Based on an analysis of these factors, the compliance with regulation of every trial was assessed. It was found that none of the trials were fully compliant. Only one single trial was assessed to be compliant to 25 per cent of the requirements on the basis that every parameter was disclosed.

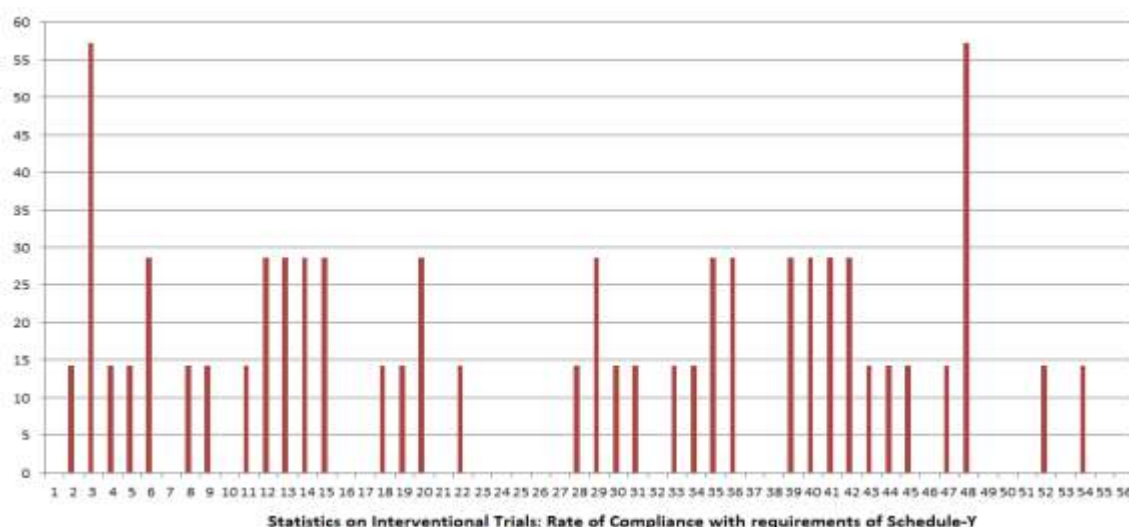


Chart 6: Extent of compliance of Disability-related trials with requirements of Schedule Y

Source: Compiled by Author using data from <http://ctri.nic.in/Clinicaltrials/pubview.php>

It was found that investigators failed to comply with several requirements of Device Trials. These are mentioned below:

1. Sponsors and sources of material or monetary funding were not mentioned or inappropriately stated in 93 per cent of the trials.
2. Only two trials mentioned that inclusion criteria would include willingness and ability to sign written informed consent form.
3. Standards of trial device are not mentioned in any of the trials. In two trials, the comparator device standards and device version were mentioned.
4. It was found that in 23 trials, the principal investigator was adequately qualified; in others, the principal investigator was found to be underqualified for partially qualified. In a few cases, the qualifications of the co-investigator were complementary.
5. Four trials were considered to be compliant with respect to inclusion/exclusion criteria. In most cases, the inclusion criteria were excessively broad without sufficient classification based on disability condition or physiognomic features.
6. The study found that only in 16 trials public query could be addressed to a superior in the research institution who would have authority to inspect or access documents pertaining to the trial. In most of the cases, the principle investigator was the only contact person mentioned for trial participants or the public to access.
7. Risk management and data management was assessed by the disclosure on how the investigator intended to manage data and privacy. Only two trials were found to be compliant in this respect.
8. Data standards and use of study data to evaluate the outcome was assessed on the basis of research design. Nearly all trials stated that the outcome would be evaluated on rating scales of global standard; however, none of the trials mentioned indigenising the scale where required.

V. STREAMLINING RESEARCH IN REHABILITATION AND ASSISTIVE TECHNOLOGIES

A parameter is a limit or boundary which defines the scope of a particular process of activity. This chapter sets the parameters for the implementation of the ICMR Guidelines, Schedule Y of the Drugs and Cosmetics Rules, 1945 and the Medical Device Rules, 2017, with reference to the requirements of the Rights of Persons with Disabilities Act, 2017 and other relevant laws.

Setting parameters would also involve adopting of new and innovative strategies to ensure that trial participation is accessible and yields reliable results. Some aspects of the RPWD Act can be adapted in research sites to encourage participants with disabilities. The site should be of universal design and disabled-friendly. Reasonable accommodation in the research site/clinic is required to enable accessibility and comfort. Examples include modifying the height of desks and equipment and hiring readers or interpreters. Special efforts to employ competent persons with disabilities in the research team would improve engagement with the disability sector. Investigators must take efforts to justify exclusion and inclusion criteria to avoid unnecessary exclusion of persons with disabilities, while ensuring that their vulnerability is not exploited. Regular participation of persons with disabilities in trials would ensure greater understanding of their vulnerability and ensure greater protection.

As the scientific research community realises that persons with disability are profoundly underrepresented in mainstream biomedical research, some researchers have proposed a Universal Design for Health Research⁵⁵. The idea is to promote routine inclusion of persons with disabilities in mainstream biomedical research without the need for adaptation or specialised design. The framework, using the definition of Universal Design in products, itself would include the use of multimedia and multi-sensory formats for recruiting participants and would promote the inclusion of participants, gathering data from participants and promote inclusion of participants with a wide range of abilities. Multiple means of communicating information on the research, multiple means for instructing participants, and providing multiple means to participants to respond to

⁵⁵ Williams, A. S and Moore, S. M. 2011. "[Universal Design of Research: Inclusion of Persons with Disabilities in Mainstream Biomedical Studies](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3320239/)", Science Translational Medicine, May 11, Vol. 3, Issue. 82. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3320239/].

interventions and instruments would enable seamless and equitable participation in trials of persons with and without disabilities.

As per Rule 49, under Chapter VII of the Medical Device Rules, 2017, clinical investigation in respect of an investigational medical device in human participants shall be conducted only in accordance with the Rules. The Central Licensing Authority would grant permission to conduct clinical investigation if it is satisfied that the requirements of the Rules have been complied with. Rule 53 provides that after grant of permission, the sponsor or investigator shall follow certain conditions:

- i. Approval by Ethics Committee prior to initiating the research.
- ii. Strict adherence to the approved clinical investigational plan, Good Clinical Practices guidelines and provisions of the 7th Schedule.
- iii. Clinical investigation should be registered with the Clinical Trial Registry of India before enrolling the first participant.
- iv. Annual status report and detailed reasons for termination should be communicated to the Central Licensing Authority.
- v. Information about any unexpected serious adverse event shall be submitted by the sponsor to the Central Licensing Authority.
- vi. In case of an injury or death, the sponsor should provide complete medical management or compensation in accordance with the rules.
- vii. The premises of the sponsor, contractors and clinical investigation sites shall be open for inspection by officers of the Central Licensing Authority.
- viii. The clinical investigation shall be initiated by enrolling first participant within a period of one year from the date of grant of permission, failing which prior permission from the Central Licensing Authority shall be required to initiate clinical investigation.
- ix. The Central Licensing Authority may impose or exempt any condition while granting permission in respect of specific clinical investigation, if considered necessary, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of clinical investigation.

The permission may be revoked, under Rule 54, if the sponsor or investigator fails to comply with any of the conditions of permission. The Central Licensing Authority may issue a warning letter giving details of deficiency found, or debar the investigator or sponsor including their employees,

subsidiaries and branches, their agents, contractors and sub-contractors to conduct any clinical investigation for such period as it thinks fit or suspend the permission for such period as it thinks fit or cancel either wholly or partly the permission.

This chapter analyses the ethical and legal considerations based on the four fundamental principles of ethical human research defined briefly in the chapter above. Here, legal and mandatory standards are applied and parameters are set from an interpretation of the relevant provisions of the enactments applicable. The ethical principles must be read together and not exclusively. For instance, to be a beneficent study, the proposed research should be undertaken with participants who have decisional autonomy and must be socially just and environmentally responsible.

Non-Maleficence and Integrity in Research

Non-maleficence in clinical trials is primarily assured through research integrity. Integrity characterises both individual investigators and the organisations and institutions in which they work. Responsible research conduct and practices include intellectual honesty in proposing, performing and reporting research. The ICMR guidelines include the *Principle of Essentiality*, whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research. The principle of essentiality *a priori* requires that the investigator honestly assess whether the research is absolutely essential after a due consideration of the existing scientific knowledge. Further, when the research is to involve persons who are vulnerable such as persons with disability, the investigator must ask searching questions with regard to essentiality. Non-maleficence also requires that the investigator abide by all provisions provided for the protection of vulnerable populations. Section 6(ii) of the Rights of Persons with Disability Act requires permission of a Committee for Research on Disability, prior to recruitment of participants or initiation of the study. Further, Rule 5 of the Central Government Rights of Persons with Disability Rules, 2017, states that no person with disability shall be a subject of research except when the research involves physical impact on his body. Research integrity includes protection of human subjects in the conduct of research and humane care of animals in the conduct of research. Scientists must refrain from research that is unlikely to benefit the participant, the society, humanity, or the environment. Article 16 of the UN Convention on Rights of Persons with Disability, which is implemented through the enactment of the Rights of Persons with Disability Act in India, provides in Article 16 that affirms the right to protection from violence and requires states to provide forms of support to people with disabilities

to help them avoid violence and abuse, and it must be accessible and appropriate to children with disabilities as well as gender sensitive. Further, all protection services must be age, gender, and disability sensitive.

Scientific misconduct is inherently harmful for the participant. Misconduct consists of serious deviations from mandatory legal principles and guidelines applicable in Indian and international scientific community for proposing, conducting and reporting research including fabrication and falsification of research data and plagiarism. Violations of human rights and theft of intellectual property also fall under scientific misconduct.

Illustration: CTRI/2013/09/004024 proposes an observational study of percentage of leg length inequalities (medically referred to Leg Length Discrepancy) among special children. The inclusion criteria provide for recruitment of children with Downs Syndrome, Cerebral palsy, Mental Retardation, Muscular dystrophy, Dystonia, visual and hearing impairment.

There is much scientific literature to prove that most human beings do not have legs of the exact same length, but most of the time we don't notice it. Large difference in leg length can cause gait problems and hip problems. The leading causes of Leg Length Discrepancy are birth conditions such as hemihypertrophy, proximal focal femoral deficiency and skeletal dysplasias and nerve problems such as cerebral palsy and polio. Trauma, infection, and tumour may also affect normal growth.

Questions may be raised as to what novel outcomes are sought in the study. Further, what rationale could be applied for the inclusion of children with hearing and visual impairment, neither of which, without attendant skeletal, birth, or nerve problems, have a significant correlation with Leg Length Discrepancy. For the latter category, adults could have been included instead of the more vulnerable category of children.

According to the ICMR guidelines, *principle of professional competence* requires that the research must be planned, conducted, evaluated and monitored throughout by persons who are competent and have appropriate and relevant qualification, experience and/or training. The Medical Device Rules, 2017 require that lab personnel and persons in-charge of equipment maintenance and device installation should also be appropriately qualified. Clause (2)(1)(ii) of the Seventh Schedule of the Device Rules required the investigators to possess appropriate qualifications, training and

experience. A qualified physician who is an investigator or sub-investigator for the investigation, shall be responsible for all investigation related decisions concerning medical issues.

Illustration: CTRI/2008/091/000231 proposes to study the effect of modified form of constraint induced movement therapy on upper extremity function in spastic cerebral palsy children with asymmetric motor impairment. The principal investigator is an assistant professor of paediatrics. It is essential for the research team to comprise, in addition, one or more developmental behavioural specialists, geneticists, neurologists and sufficient number of physical and occupational therapists trained in the use of Constraint Induced Movement Therapy. A developmental Behavioural specialist would be trained to evaluate the developmental issues and a neurologist would be required to assess the extent of contribution of neurological issues to the condition.

The ICMR guidelines further propose the *principle of transparency and accountability* whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/audit. The Medical Device rules also require accountability in terms of use, disposal and storage of the investigational product.

As per the Medical Device Rules, the responsibilities of sponsors are onerous. They are responsible for maintaining quality and ensuring adherence to the research protocol. They are also charged with the task of maintaining records and reporting adverse events to the appropriate authorities. If research harm is reported, they must ensure medical management of the injury or compensation where relevant. The responsibilities of investigators run concomitantly. They are responsible for keeping the sponsor and the institution informed at all times of the status of the study and any adverse event, deviation, or non-compliance. Ethics committees are responsible for reviewing and approving proposals after ensuring the rights, safety and well-being of the participants. They are also charged with continuous monitoring of the study and can require updates or visit sites. They may also revoke approval on learning of deviations or harm to the participant.

Research integrity also requires the investigator to examine the data with objectivity and be guided by results and outcomes of the research rather than by preconceived outcomes. Appendix X of Schedule Y of the Drugs and Cosmetics Rules, states that the protocol must provide details of the statistical approach to be followed, including sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints and safety endpoints. Statistical analysis requires details of how the results will be analysed and reported along with the description of statistical tests to be used and the methods used for missing data; method of evaluation of the data for treatment failures, non-compliance, and subject withdrawals; rationale and conditions for any interim analysis if planned. Under the Medical Device Rules, Clinical evidence means clinical data and the clinical evaluation report that supports the scientific validity and performance for the intended use of the device.

Illustration: CTRI/2018/01/011153 proposes to study the effectiveness of interventions for scapulothoracic rehabilitation in addition to conventional rehabilitation on upper limb functional recovery in acute stroke subjects. The outcome is sought to be measured with the *Stroke Upper Limb Capacity Scale*.

The scale also called SULCS was first developed in Dutch⁵⁶ and translated into English. For the scale to be appropriate for an Indian study, an Indian version⁵⁷ (site specific owing to language differences) would have to be developed using the process of forward-backward translation, after authorisation from the author of the original scale. Subsequently, the semantic and linguistic adaptation of the SULCS would have to be executed and reliable cultural adaptation demonstrated, prior to its use in the current study. Use of improper tools and datasets reduces the reliability and validity of the study.

While persons with disability participating in clinical trials are guaranteed all protections available to persons without disability, the additional parameters set in respect of the criteria of non-maleficence when the study includes persons with disability are:

⁵⁶ Roorda, L. D. et al. 2011. "[Measuring Upper Limb Capacity in Poststroke Patients: Development, Fit of the Monotone Homogeneity Model, Unidimensionality, Fit of the Doubt Monotonicity Model, Differential Item Functioning, Internal Consistency, and Feasibility of the Stroke Upper Limb Capacity Scale, SULCS](https://www.archives-pmr.org/article/S0003-9993(10)00866-X/pdf)", *Archives of Physical Medicine and Rehabilitation*, February, Vol. 92. Pg. 214-27. [https://www.archives-pmr.org/article/S0003-9993(10)00866-X/pdf].

⁵⁷ Branco, J.P. et al. 2017. "[Assessing upper limb function: transcultural adaptation and validation of the Portuguese version of the Stroke Upper Limb Capacity Scale](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5543451/)", *BMC Sports Sci Med Rehabil*, August 3, Vol. 9, Issue. 15. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5543451/].

- a) Participation of persons with disability in research must follow the strict principles of essentiality of their involvement.
- b) Prior permission of the Committee for Research must be sought.
- c) Outcomes must be evaluated on the bases of tools which have undergone linguistic and cultural adaptation, and whose scientific validity has been proved.
- d) The investigator and sponsor must ensure transparent, accountable and responsible publication of outcomes.
- e) Internationally accepted standards of protection and treaty obligations protecting rights of persons with disability must be strictly adhered to.

Autonomy and Informed Consent

Article 21 of the Indian Constitution states that no person shall be deprived of his life or personal liberty except according to procedure established by law. *K.S. Puttaswamy V. Union of India*⁵⁸, provides the most recent interpretation on autonomy and decisional autonomy in India. A three-judge bench considering the constitutional challenge to the Aadhaar Card scheme on the grounds of violation of privacy, found that ‘it has become essential for us to determine whether there is any fundamental right of privacy under the Indian Constitution,’ and decided to place the question before the nine-Judge Constitution Bench. In the course of the discussion on privacy, the nine-Judge Constitution Bench extensively considered the question of autonomy of the individual and decisional autonomy. The court found that autonomy of the individual is conditioned by her relationships with the rest of the society. Those relationships may and do often pose questions to autonomy and free choice. The Supreme Court cited with approval, the correlation of human dignity with autonomy as expressed by Aharon Barak, former Chief Justice of the Supreme Court of Israel: The best decisions on how life should be lived are entrusted to the individual. The duty of the state is to safeguard the ability to take decisions—the autonomy of the individual—and not to dictate those decisions⁵⁹.

The court goes on to relate privacy and decisional autonomy. Privacy recognised the autonomy of the individual and the right of every person to make essential choices which affect the course of life. The Judges cite with approval the South African decision in *National Coalition for Gay and*

⁵⁸ *Justice K S Puttaswamy (Retd.), and Anr. Versus Union of India and Ors*, **Supreme Court of India**, August 24, 2017. [<https://indiankanoon.org/doc/91938676/>].

⁵⁹ **Coffey, D.K. 2015.** “Aharon Barak, Human Dignity – The Constitutional Value and the constitutional Right”, *Cambridge University Press*, Vol. 38, Pg. 360.

Lesbian Equality v Minister of Justice (1999), which connected equality to privacy, stating that discrimination leads to invasion of privacy. The Court also referred to Anita Allen's formulation that Privacy has distinct connotations, including spatial control (the creation of private spaces), decisional autonomy (that comprehends intimate personal choices as well as choices expressed in public), and informational control which empowers the individual to use privacy as a shield to retain personal control over information pertaining to the person. The Court states that the inviolable nature of the human personality is manifested in the ability to make decisions on matters intimate to human life.

The Rights of Persons with Disability Act, 2017, was enacted to give effect to the UN Convention on the Rights of Persons with Disabilities. The Convention's principles, extracted in the preamble to the Act, including respect for difference and acceptance of persons with disabilities as part of human diversity and humanity, and respect for the evolving capacities of children with disabilities. The Convention in Article 3 also affirms the right of children with disability to preserve their identity, a principle enshrined in the preamble of the Right of Persons with Disability Act. Article 22 of the Convention on Rights of Persons with Disability affirms the right of persons with disability to have the same right to privacy, including privacy in respect of persona, health and rehabilitation information.

The right to identity of an individual is associated with other rights such as the rights to a name, nationality, juridical personality, family, gender, culture, and language but may encompass any one of these. The right of children to their origin or their status of parentage enable children to develop a full sense of identity, guaranteed under the Convention on the Rights of the Child. In addition, children and persons with disability are entitled to a disability-sensitive identity. This means that children/persons with disability must viewed as persons capable of decisional autonomy within the scope of their evolving capacities. A general view of persons with disabilities as victims, unable to do things, childlike or 'special', dilutes and undermines their identity as independent persons. Assessment of decisional autonomy of persons with disability is a task for specialists with experience and/or training in such assessment.

The ICMR guidelines define the *principle of voluntariness* as respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are safeguarded. Appendix V of Schedule Y of the Drugs and Cosmetics Act states that 'in all trials, a freely given,

informed, written consent is required to be obtained from each study subject.' The subject's consent must be obtained in writing using an 'informed consent form'. The informed consent form must contain a statement that the study involves 'research', and the descriptions of the procedures to be followed. In order to give their consent, the participants must have adequate information. The Medical Device Rules, 2017 requires the investigator to provide information about the study verbally and through the patient information sheet, in a language that is non-technical and is understandable by the participant. The participant must be informed of any reasonably foreseeable risks or discomforts. The participant must know if there is any benefit to him from the research, and also what specific appropriate alternative procedures or therapies are available to him. There should be a statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records. The subject must also be informed of their responsibilities. The investigator must inform the participant that participation is voluntary and that the participant can withdraw at any point from the trial, with required medical management.

Additionally, the Right to Persons with Disabilities Act defines communication (Section 2(f)) as including means and formats of communication, languages, display of text, Braille, tactile communication, signs, large print, accessible multimedia, written, audio, video, visual displays, sign language, plain-language, human-reader, augmentative and alternative modes and accessible information and communication technology. Section 6(2) (i) of the Rights of Persons with Disabilities Act states that no person with disability shall be a subject of any research without his or her free and informed consent obtained through accessible modes, means and formats of communication.

Yet another aspect of informed consent process is decision-making capacity, which is independent of the freedom to make a decision. Decisional capacity is the ability of the participant to make decisions regarding their participation. Capacity to make decision can be readily judged on certain factors such as majority of participant, financial resources and health condition of participant. Certain other elements of capacity cannot be readily assessed. These are: understanding of the medical issue and the scientific solution, appreciation of the risks and benefits, reasoning capacity of the individual, values and choice.

Despite being provided the information in non-technical language and accessible modes of communication, the proposed participant may find it difficult to understand the medical and

scientific logic or may not understand that they are ‘free’ to consent. The ability to weigh risks and benefits is also dependent on the prior experience of taking responsible decisions and evaluate consequences. Again, patients may rely on their doctors or caregivers to provide the reasoning and evaluation, thereby ceding control over their choice. In the case of persons with certain types of disabilities, the ability to communicate their decision may be compromised.

Illustration: CTRI/2010/09/003019 The trial proposes to study the *feasibility* of Functional Electrical Stimulation (FES) in chronic stroke patients. The protocol includes intervention in the form of application of FES using indigenous low cost NIOH-IITKGP FES device for 30 minutes for five days in a week over a 24-week period. The comparator device is the EU certified CEFAR COMPLEX device. The goal is to reduce or eliminate impact of foot drop.

A feasibility study, in general parlance, is a process of evaluating the possibility of conducting a particular clinical program/trial in particular regions with the overall objective of optimum project completion in terms of timelines, targets and costs⁶⁰. Feasibility studies may be conducted at programme level, study level, site or investigator level. Study-level feasibility studies include the assessment of clinical aspects, regulatory aspects, technical aspects and operational aspects of the proposal. Investigator competency and collegiality between team members may also be studied. In the illustration, the term feasibility study is inappropriately applied to what appears to be a bio-equivalence study between an EU approved CEFAR COMPLEX FES device with an indigenous and non-standard device. The inappropriate use of technical terminology vitiates the informed consent process.

The principle of voluntariness also requires that investigators take into consideration the participant’s experience, opinions, and concerns when conducting the trial. Section 4(2) of the Rights of Persons with Disabilities Act requires that the appropriate government and local authorities shall ensure that all children with disabilities shall have right on an equal basis to freely express their views on all matters affecting them and provide them with appropriate support keeping in view their age and disability. The terms ‘subject’ and ‘human subject’, though a legally valid appellation for persons who volunteer to participate in a trial, are not preferred for use by ethics committees. Where the trial involves patients, it is acceptable to use the term patient. In

⁶⁰ Rajadhyaksha, V. 2010. “[Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146075/)”, *Perspective in Clinical Research*, July-September, Vol. 1, Issue. 3, Pg. 106-109. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146075/].

other circumstances, persons participating in trials voluntarily to enhance scientific knowledge or to benefit society in some way may be rightly called participants. The ICMR Guidelines, 2017 uses the term participants. In the context of persons with disability, the tendency is to treat them as 'unhealthy' or as patients. It is important to understand that for a disabled person, the disability is normal and 'healthy' condition, though the said person may require additional assistance; the health care needs of disabled persons are comparable to those without disability. Decisional competent adult participants who freely volunteer to participate in a trial are not without duties and obligations. It is the duty of participants to be responsible in complying with study requirements and fulfilling other obligations that they undertake, such as reporting and recording. The responsibility to protect themselves from self-harm by non-compliance is also cast on the participant. The participant should also inform the investigator or site monitor about any impediments to their compliance such as financial constraints in travelling for study visits. Compliance with study requirements is also essential to ensure optimum outcome and, thereby, avoid causing harm to others. For instance, a participant who, demonstrating a pattern of violence, fails to comply with his dose requirements, may cause harm to those around him.

Illustration: CTRI/2011/11/002137 proposes the use of Nintendo Wii gaming console for rehabilitation of children with cerebral palsy. Inclusion criteria includes persons of both sexes between the ages of three years and 20 years. Although children at the lower end of the inclusion criteria for age may not be able to effectively participate (playing tennis or boxing on Wii), their participation is purely voluntary and they may, therefore, not be referred to as 'patients'. While participating, it is the duty of the investigator to take into consideration their voluntariness and willingness to participate in every session—which is 45-60 minutes per day, six days a week for three weeks.

The additional parameters set for involvement of persons with disability in trials and studies are:

- a) Treatment of persons with disability as healthy volunteers where appropriate.
- b) Not treating failure to communicate with persons with disability as lack of decisional capacity or decisional autonomy on the part of the participant.
- c) Disabled persons with high support needs may, at times, be accommodated in institutions and be subject to gatekeeping by personal caregivers, caretakers, and staff. Such potential participants should be enabled and empowered to exercise autonomy and decisional capacity. If gatekeeping is deliberate to ensure that persons with disability are protected,

such as by the Committee for Research on Disability under the Rights to Persons with Disability Act, then investigators must be scrupulous in adhering to the principles of access laid down by them.

- d) Persons with disability must be entitled to disability-sensitive data management systems and privacy.

Beneficence and Risk Minimisation

The value and benefit of research is dependent on the integrity of the researcher. According to the ICMR guidelines, responsible conduct of research involves values, policies, planning and conducting research, reviewing and reporting research, and responsible authorship and publication. Values of research include honesty, accuracy, efficiency, fairness, objectivity, reliability, accountability, transparency, personal integrity, and knowledge of current best practices.

The ICMR guidelines state the *principle of maximisation of benefit* as due care taken to design and conduct the research in such a way as to directly or indirectly maximise the benefits of the research to the participants and/or to society. The *principle of institutional arrangements* requires institutions where the research is being conducted to have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds, and training opportunities. The *principle of ensuring privacy and confidentiality* requires that privacy of the participant, his/her data and records are kept confidential and access is limited to only those authorised. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.), privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the life of an individual supersedes the right to privacy of a research participant. The *principle of social responsibility* requires that research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb the harmony in community relationships. The ICMR guidelines state that research should not lead to social, racial or ethnic inequalities. The *principle of environmental protection* requires that researchers are accountable for ensuring protection of the environment and resources at all stages of the research in compliance with existing guidelines and regulations. Readily measurable benefits of devices and drugs must be measured at every stage and the principle of beneficence requires that when there is sufficient demonstration or confirmation of benefits

according to outcome endpoints, the trial may be terminated even if the anticipated duration of the trial is not completed.

Benefits to the individual, community, or society refers to any sort of favourable outcome of the research, whether direct or indirect. The social and scientific value of the research should justify the risk or discomfort. A risk management plan should be put in place and investigators and sponsors must provide reasonable evidence of potential benefit. The Medical Devices Rules requires that the risks and benefits associated with the use of the medical device should be described. The risk analysis should be periodically updated as risks are identified as per the risk management plan. In the case of a medical device, the overall safety evaluation should also involve a benefit evaluation and a risk-benefit evaluation. In fact, the Rules require that anticipated clinical benefits of both the device and the investigation must be set out in the brochure. Based on these disclosures, the Ethics committee should attempt to maximise the benefits and minimise the risks so that risks are balanced to lead to potential benefit to the participant and/or society.

Illustration: CTTRI/2017/12/010970 proposes the development of a device for physically challenged people for independent indoor and outdoor mobility. Target segment includes wheelchair users who have suffered spinal cord injury, cerebral palsy, multiple sclerosis, muscular dystrophy and old age. In addition, the inclusion criteria state the age criteria as 18 to 70 years, persons of both genders who are between four and six feet tall and weigh between 40 and 100 kg.

It is important to note that the WHO wheelchair guidelines state (1.8) Types of wheelchair – no single model or size of wheelchair can meet the needs of all users, and the diversity among users creates a need for different types of wheelchair. Basic types of wheel chairs are temporary user wheelchairs, wheel chair for long term use, and wheelchair designed for user with postural support needs. It is suggested that unless the investigator proposes a different model and size for each weight, age and condition, this would not be beneficial trial.

Besides the general parameters for beneficence, trials involving persons with disability should adhere to the following parameters:

- a) Disability sensitive trials where investigators are trained in disability studies and have an understanding of disabilities.

- b) Disabled persons with different types of disability may be perceived by non-medical persons as having similar conditions; for example, all wheelchair users may be classified as one group. Investigators should not make such mistakes and should take the help of medical and other experts in proper classification.
- c) Maximising benefits also means aligning with national goals or goals set by statutes. For instance, investigators interested in supporting the disability sector must consider developing universal design products.
- d) All possible steps must be taken towards standardising the device to global acceptable industrial standards in respect of safety and performance, prior to recruitment of persons with disability.

Justice

The *principle of non-exploitation* requires that research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured. The principle of distributive justice as elucidated in the ICMR guidelines require that efforts be made to ensure that individuals and communities invited for research are selected in such a way that the benefits and burdens of research are equitably distributed. Vulnerable individuals/groups should not be included in research to solely benefit others who are better-off than themselves. Plans for direct or indirect benefit sharing in all types of research with participants, donors of biological materials or data should be included in the study, especially if there is a potential for commercialisation. The ICMR guideline states that this should be decided *a priori* in consultation with the stakeholders and reviews by the ethics committee.

Exploitative and unjust research involving persons with disability has been addressed in the Rights to persons with disabilities Act. As per Section 7 of the Rights of Persons with Disabilities Act, the appropriate government shall take measures to protect persons with disabilities from abuse, violence and exploitation and to prevent the same. Further, the government is required to take cognizance of such incidents and provide legal remedies available against such incidents. Read with Section 6, where the persons have been subject to research without free and informed consent and prior permission of the Committee for Research, the government can take action to punish the wrong doers as well as protect and rehabilitate the victims of such incidents. It may be understood

that persons with disabilities are entitled to participate equally with persons without disabilities in trials of experimental life-saving drugs and devices, and those that may improve the quality of life.

The ICMR guidelines require the community's health needs and expectations are addressed and the access to research benefits is provided to the community. Section 28 of the Rights of Persons with Disabilities Act requires the appropriate government to initiate or cause to be initiated research and development through individuals and institutions on issues which shall enhance habilitation and rehabilitation and on such other issues that are necessary for the empowerment of persons with disabilities. The intent of this Section is to promote R&D towards empowerment of persons with disabilities and to improve their habilitation and rehabilitation. Again, there is focus on developing consumer products and accessories, and electronic goods and equipment which are meant for everyday use in universal design (Sections 42 and 43). Universally designed products, environments, and services are usable by all people to the greatest extent possible without the need for adaptation and specialised design for a particular group of persons with disabilities.

Justice also requires that institutions develop policies and institutional mechanisms to address scientific/research misconduct. All allegations of misconduct must be investigated and such investigations, according to the ICMR guidelines, must be timely, fair, and transparent, and the results should be made available in the public domain. *Illustration:* CTTRI/2011/07/001860 proposes to compare low cost treatment regimen with standard regimen in patients with hepatorenal syndrome. The design of the study is a randomised controlled trial.

It may be noted while clinical trials can provide important information on the cost effectiveness of a treatment, along with the clinical value of the treatment and how the treatment improves quality of life, the ethical implications of offering to a potential participant of limited means a 'low-cost' treatment vis-à-vis a higher cost standard treatment must be seriously considered. When a trial is titled 'low-cost', it causes an inherent and inevitable bias in recruitment which cannot be justified by the inclusion criteria. A patient who can afford the more expensive 'standard' treatment would not agree to participate in a low-cost treatment trial. The low-cost of availability of the drug, device, or treatment regime is not guaranteed by the title or the researcher, but ultimately the product development, manufacturing, and retail market.

The operational costs of clinical trials are cheaper in India and other BRICS countries. The locations offer access to larger number of patients with quicker enrolment, while enrolment in the US. or the EU is challenging and time consuming. Lower standard of care in regular hospital settings in India and availability of the trial drug or device free of cost may also encourage patients to participate in trials. In such circumstances, deliberately titling a study low-cost instead of stating the scientific fact is unjust and exploitative, as patients or participants with limited means will be willing to participate for the opportunity of dubious treatment instead of the standard treatment which they cannot afford. In addition to other parameters, investigations involving persons with disability should adhere to the following parameters:

- a) The investigation must only disclose, validate, and evaluated safety and efficacy based on scientific facts and requirements. Economic factors such as cost cannot be validated in a clinical trial. The use of euphemistic qualifiers such as low-cost and indigenous for non-standard should be avoided.
- b) Investigators intending to support the disability sector with their innovations and ideas, should engage with the community and receive their input on the unmet needs of the sector.
- c) Investigators should ensure that devices developed are of standard quality in order to ensure that they are available in the market (whether for profit or not). This is justice to the use of participants with disability.
- d) Stakeholders must ensure that persons with disability recruited in a trial equally with non-disabled persons receive the same degree of care medically, but that in addition, they are offered support and assistance as required for their fullest participation.

GLOSSARY OF TERMS

1. Rehabilitation Engineering

Rehabilitation engineering is the systematic application of engineering sciences to design, develop, adapt, test, evaluate, apply, and distribute technological solutions to problems confronted by individuals with disabilities in functional areas, such as mobility, communications, hearing, vision, and cognition, and in activities associated with employment, independent living, education, and integration into the community.

It is also treated as a subspecialty of biomedical engineering, which is the application of engineering principles and design concepts to medicine and biology, and seeks to close the gap between engineering and medicine, combining design and problem solving (traditionally engineering subjects) to healthcare areas such as diagnoses, monitoring and therapy.

Section 2(za) of the Rights of Persons with Disabilities Act, 2016 defines “rehabilitation” as a process aimed at enabling persons with disabilities to attain and maintain optimal, physical, sensory, intellectual, psychological, environmental, or social function levels.

In other contexts, rehabilitation may also refer to the action of restoring someone to health or normal life through training and therapy after imprisonment, addiction, or illness. The WHO also alerts us to a distinction between ‘habilitation’, which aims to help those who have acquired disabilities congenitally or early in life to develop maximal functioning, and ‘rehabilitation’, where those who have experienced loss in function are assisted to regain maximal functioning⁶¹. The Rights of Persons with Disabilities Act, 2016, in Section 28, requires the Government to initiate research and development which shall enhance habilitation and rehabilitation and on other issues necessary for the empowerment of persons with disabilities. For the purpose of this study rehabilitation covers both types of intervention. Rehabilitation measures in this chapter are broadly divided into three categories:

- I. rehabilitation medicine
- II. therapy
- III. assistive technologies.

⁶¹ World Health Organisation. 2011. “[Chapter 4 – Rehabilitation](http://www.who.int/disabilities/world_report/2011/chapter4.pdf)”, pg. 95-133. [http://www.who.int/disabilities/world_report/2011/chapter4.pdf].

I. Rehabilitation Medicine

Rehabilitation medicine is a discipline of medicine and practiced by a trained doctor and includes the core clinical skills of making a diagnosis, formulating a prognosis, and providing expert medical care. It entails the treatment of disabling conditions, active management of disability, and prevention of secondary complications. Doctors in rehabilitation medicine may also work with children and the elderly. The four main clinical areas in rehabilitation medicine are: neurological, musculoskeletal, amputee, and rehabilitation following spinal cord injury. Sub specialities may include sports injuries and hospice and palliative care. Services are also provided to people with long term neurological conditions such as multiple sclerosis and cerebral palsy, generally as outpatients within community settings.

Many doctors working in this branch of the specialty also provide medical input to orthotics clinics, wheelchair centres, and other services providing technological solutions. They may also be required to provide information, support, and counselling for patients and their families and carers and lead multidisciplinary teams.

II. Rehabilitation Therapy

Doctors in rehabilitation medicine work closely with many other medical specialties, healthcare professionals and other agencies to assess and provide interventions to individuals with complex disabling conditions, towards optimising recovery after severe injuries, improve function, and promote participation in society in the longer term for all people with conditions that give rise to disability. Rehabilitation therapy includes

- Physical therapy to help your strength, mobility and fitness
- Occupational therapy to help you with your daily activities
- Speech-language therapy to help with speaking, understanding, reading, writing and swallowing
- Cognitive rehabilitation therapy is provided to help those with traumatic brain injuries or other cognitive impairment
- Treatment of pain

III. Assistive Technology

Assistive technology refers to technologies and principles that meet the needs of and address the barriers confronted by individuals with disabilities in a range of life areas. Assistive technology is

often associated with education, rehabilitation, employment, transportation, independent living, and recreation⁶².

Assistive technology device is any equipment, product or system that is used to increase, maintain or improve functional capabilities of individuals with disabilities. Assistive technology can be high or low, and can be procured, built, or customised or personalised. Assistive technology and devices are constantly undergoing evolution based on the user's health or environment, changing level of independence of the user, and improvement or upgradation of technology. Normally, users are assisted in the selection, acquisition and use of an assistive device by persons performing assistive technology services. These may include doctors, para-medical assistants and specially trained assistants. Over a period of time, caregivers of the disabled persons also learn to assist the user.

2. Persons with Disability

The Rights of Persons with Disabilities Act, 2016, defines several categories of persons with disabilities.

2(r) “person with benchmark disability” means a person with not less than 40 per cent of a specified disability where specified disability has not been defined in measurable terms and includes a person with disability where specified disability has been defined in measurable terms, as certified by the certifying authority;

2(s) “person with disability” means a person with long term physical, mental, intellectual or sensory impairment which, in interaction with barriers, hinders his full and effective participation in society equally with others;

2(t) “person with disability having high support needs” means a person with benchmark disability certified under Clause (a) of Sub-section (2) of Section 58 who needs high support; and

2(zc) ‘specified disability’ which includes the disabilities specified in the Schedule.

⁶² Engineers Australia. “[National Committee on Rehabilitation Engineering \(NCRE\)](https://www.engineersaustralia.org.au/Communities-And-Groups/National-Committees-And-Panels/Rehabilitation-Engineering)”.
[<https://www.engineersaustralia.org.au/Communities-And-Groups/National-Committees-And-Panels/Rehabilitation-Engineering>].

The Schedule considerably expands the definition of persons with disability to include leprosy cured person, and persons with cerebral palsy, dwarfism, and muscular dystrophy. Victims of acid attacks are included as are persons suffering from Parkinson's disease and blood disorders, including haemophilia, thalassemia, and sickle cell disease.

The Act also provides for registration of organisations of disabled persons. Under Section 2(z), "registered organisation" means an association of persons with disabilities or a disabled person organisation, association of parents of persons with disabilities, association of persons with disabilities and family members, or a voluntary or non-governmental or charitable organisation or trust, society, or non-profit company working for the welfare of the persons with disabilities, duly registered under an Act of Parliament or a State Legislature.

3. Engineering and Engineering Technology

Engineering is practice or profession of applying mathematical and scientific knowledge to solve problems. Engineering is concerned with the design, building and use of engines, machines and structures. Engineering technology, a subset of the technological field, requires the application of scientific and engineering knowledge and methods combined with technical skills in support of engineering activities. Technologists are more likely than engineers to focus on (post-development) implementation or operation of a technology.

4. Technology Research

Technology is the application of scientific knowledge for solving practical problems, and includes tools, process actions, methods, systems and devices. The application of technology results in artifacts or products. The development of technology draws upon many fields of knowledge besides science, including history, language, culture and the law, as technologies must satisfy requirements such as utility, usability, and safety.

Research is the systematic investigation into and study of a specific problem, concern, or issue using the scientific method. Technology research includes study into materials and users in order to design usable products. Applied research is aimed at developing tools and to test equipment and procedures, and at procedures so as to provide solutions to specific technical problems.

Technology research includes a number of steps beginning with blue-sky thinking, tentative technical solutions, proof-of-concept testing and confirmation towards product development.

Design and development of products for specific populations begins with needs assessment of users and technology, establishing criteria for design, design of the equipment or technology solution, and product testing for performance, strength, safety, and durability. This is followed by user trials, provision of devices to users, and long term follow up with users.

5. Clinical Trial

The term 'clinical' relates to the observation and treatment of actual patients rather than theoretical or laboratory studies. The Drugs and Cosmetics Rules, 1945, 122DAA defines Clinical Trial as a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug.

Section 3b of the Drugs and Cosmetics Act, 1940, defines 'drug' as

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

6. Research under the RPWD Act

Section 6 of the RPWD Act protects persons with disabilities from torture, cruelty, and inhuman and degrading treatment. As per S. 6(2), no person with disability shall be a subject of any research without, -

- (i) his or her free and informed consent obtained through accessible modes, means and formats of communication; and
- (ii) prior permission of a Committee for Research on Disability constituted in the prescribed manner for the purpose by the appropriate Government in which not less than half of the members shall themselves be either persons with disabilities or members of the registered organisation as defined under section 2(z). This provision specifically enforces ethical standards in biomedical research on persons with disabilities; protection from abuse, violence and exploitation is covered under Section 7. Under Rule 5 of the Central Government Rules under the RPWD Act, no person with disability shall be a subject of research except when the research involves physical impact on his body.

As per Rule 4 of the Central Government Rules under the RPWD Act, the central committee for Research on Disability shall consist of

- (i) an eminent person having vast experience in the field of science or medicine, to be nominated by the Central Government, ex officio-Chairperson;
- (ii) nominee of the Director General of Health Services not below the rank of Deputy Director General –Member;
- (iii) four persons drawn from National Institutes representing physical, visual, hearing and intellectual disabilities, to be nominated by the Central Government – Members;
- (iv) five persons as representatives of the registered organisations, from each of the five groups of specified disabilities in the Schedule to the Act, to be nominated by the Central Government – Members: Provided that at least one representative of the registered organisations is a woman;
- (v) the Director, Department of Empowerment of Persons with Disabilities, New Delhi shall be the Member Secretary.

The Chairperson may invite any expert as a special invitee. The term of office of the nominated members shall be for a period of three years.

Rule 4 of the (Draft) Tamil Nadu State Rules under the RPWD Act simply states that the State Government shall constitute a Committee for Research on Disability for the purpose of section 6(2)(ii) of the Act.

Under Section 17, putting in place specific measures to promote and facilitate inclusive education, the Act casts a duty on the appropriate Government and the local authorities to take measures for the purpose of section 16 including in clause (j) to promote research to improve learning.

Section 16 requires the appropriate government and the local authorities to endeavour that all educational institutions funded or recognised by them to provide inclusive education to children with disabilities.

With regard to healthcare, the Act, in Section 25(2) requires the appropriate Government and the local authorities to take necessary measures to promote healthcare and to prevent the occurrence of disabilities and for the said purpose – (a) undertake or cause to be undertaken surveys, investigations and research concerning the cause of occurrence of disabilities. Read with the other clauses in the section including promoting various methods for preventing disabilities, screening

children, taking measures for care of mother and child, providing healthcare during the time of natural disasters and ensuring the availability of essential medical facilities for life saving emergency treatment and procedures, this clause ensures that such the findings of such research or investigation should be, after due validation, used to improve the health care levels in the country.

Again, the Tamil Nadu (Draft) Rules, in Rule 19 states that the State Government shall initiate or cause to be initiated research and development through individuals and institutions on issues which shall enhance habilitation and rehabilitation and on such other issues which are necessary for the empowerment of Differently Abled persons.

Section 28 of the Rights of Persons with Disabilities (RPWD) Act, 2016, makes it mandatory for the appropriate government to initiate or cause to be initiated research and development through individuals and institutions on issues which shall enhance habilitation and rehabilitation and on such other issues which are necessary for the empowerment of persons with disabilities. The Department of Empowerment of Persons with Disabilities has launched the above scheme in January, 2015 with the objective to promote research of service models and programmes on the basis of life cycle needs., holistic development of the individuals and their families and creating an enabling environment; and for the empowerment of persons with disabilities and promote research in prevention and prevalence of disability and the application of science and technology to the development of indigenous, appropriate aids and appliances. The Scheme has two components:

- (i) Research and development of assistive technology and product development devices: and
- (ii) Scheme for study/ research/ survey/ internship and periodical collection of data related to disability.

Section 43 of the RPWD Act says that the appropriate Government shall take measures to promote development, production and distribution of universally designed consumer products and accessories for general use for persons with disabilities.

According to the provisions of Section 47, it is the duty of the appropriate government to endeavour to develop human resource for the purposes of this Act, and mandate training on disability rights for all stakeholders. In particular, clause (2) requires all universities to promote teaching and research in disability studies including establishment of study centres for such studies.

The Central and State Advisory boards to be constituted under Chapter XI of the Act must include the heads of institutes of research such as the National Institute of Rehabilitation Training and Research, Cuttack, and the Indian Sign Language Research and Training Centre, New Delhi.

Among the functions of the Chief Commissioner under Section 75 are the duty to (f) undertake and promote research in the field of the rights of persons with disabilities. A similar role is envisaged for the State Commissioner in Section 80(e). Further under Section 100, the Central Government can make rules to provide for the 2(a) manner of constituting the Committee for Research on Disability, while the State Government has similar powers under Section 101(2)(a). Under Rule 60 of the Tamil Nadu (Draft) Rules, the State Commissioner has a duty to undertake and promote research in the field of the rights of persons with disabilities.

7. CDSCO

The Central Drugs Standard Control Organisation (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control. It is headed by the Drugs Controller General.

Major functions of CDSCO includes regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licenses as Central License Approving Authority is exercised by the CDSCO headquarters.

ACTS AND RULES

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[The title of this Policy Report was corrected on December 26, 2018].



Swapna Sundar's research explores the ethical issues surrounding research in rehabilitation engineering and assistive technologies involving persons with disabilities. She also proposes to examine the legal and constitutional aspects of conducting research on persons with disabilities. Swapna is a lawyer by training and is a member (legal) of several Institutional Ethics Committees in Chennai.

She is also the CEO of IP DOME Strategy Advisors Pvt. Ltd., a company that supports protection and commercialisation of inventions. In this capacity, Swapna emphasises the need for compliance with industry standards and domestic regulatory requirements for new medical and assistive devices.

Swapna's past work has included a Tamil Nadu Urban Development Project (TNUDP) grant study on Rationalisation of Trade Licensing in Tamil Nadu, and strategies for deploying IP in India for the UK Intellectual Property Office. Her articles on Technology and Law have been published in *The Hindu Business Line* and in the *Indian Journal of IP Law*. Apart from teaching IP Law at NALSAR and in various institutions such as VIT and Symbiosis Law School, she has taught an elective in Technology and Law at the ACJ-Bloomberg Course on Business and Financial Journalism in 2017. She is the author of the IP *Smart Workbook - the Lab to Market Guide to Inventing*.

In addition to Technology and Law, Swapna has an interest in governance, smart cities, crowd control and policing and has had articles published in newspapers and the *Economic and Political Weekly*. She is the author of *Occupy Marina!* a book exploring the various issues surrounding the Jallikattu Protest on the Marina in Chennai, Tamil Nadu, in January 2017. She has recently been invited by the National Institute of Epidemiology (ICMR-NIE) to provide legal consultation in their project proposing to update guidelines and amend the provisions relating to public gatherings in the Tamil Nadu Public Health Act, 1939.



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