HUMAN ORGANOIDS AND THE LEGAL VACUUM: PROPERTY, PERSONHOOD AND THE REGULATORY CRISIS INDIA CANNOT AFFORD TO IGNORE

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ABSTRACT

Human organoids is miniaturised, three-dimensional organ-like structures grown from human stem cells which represent one of the most consequential scientific developments of the twenty-first century. Their applications span disease modelling, drug discovery, personalised medicine, and transplantation research. Yet, beneath this remarkable scientific promise lies a profound and largely unaddressed legal crisis: the law does not know what a human organoid is. Is it human tissue? Is it a laboratory product? Is it a person? Or is it something entirely novel that existing legal categories cannot contain? In India, this question is particularly urgent. The "Patents Act, 1970", "the Drugs and Cosmetics Act, 1940", "the ICMR-DBT National Guidelines for Stem Cell Research" and "the DPDPA, 2023:" collectively form a patchwork that neither defines nor governs organoids in any meaningful way. No Indian court has ruled on their legal status. No Indian statute directly addresses their patentability, ownership, or ethical use. This article examines the legal vacuum surrounding human organoids in India, analyses the inadequacy of the existing regulatory framework, draws on international jurisprudence particularly the most paramount American case of "Moore v. Regents of the University of California (1990)" and at the same time, it also examines China's leading "Human Organoid Research Ethical Guidelines (2025)" and proposes a sui generis legal framework tailored to the Indian context. The article argues that India's silence on this question is not merely a regulatory gap but a ticking legal time bomb whose detonation could harm scientific innovation, patient rights, and constitutional dignity simultaneously.

Introduction

In 2013, the laboratory of Hans Clevers at Utrecht University grew the world's first functional human intestinal organoid from a single adult stem cell. What began as a scientific marvel has since become a global research staple: today, organoids of the brain, kidney, liver, lung, pancreas, and retina are being cultivated in laboratories across the world including in India.[1] The scientific literature on organoids is vast and growing. The legal literature, particularly from an Indian perspective, is virtually non-existent.

This absence of legal scholarship is not a trivial omission. When a researcher at an Indian institute grows a brain organoid from a patient's induced pluripotent stem cells (iPSCs), a cascade of unresolved legal questions immediately arises. Does the patient retain any rights over that organoid? If organoid is commercialised, does the patient share in the profits? Can the method of creating the organoid be patented? If the organoid is modified through gene-editing and develops neural activity, what then? Is it closer to a laboratory product or to a biological entity deserving moral consideration?

Globally, scholars and policymakers are beginning to grapple with these questions.[2] As of April 2025, China is one of the pivotal countries in the world to issue dedicated national governance framework for human organoid research.[3] In 2024, the United Kingdom's "Nuffield Council on Bioethics" issued a policy memo addressing the ethical concerns of neural organoids. Earlier, in 2021, the "International Society for Stem Cell Research (ISSCR)" revised and strengthened its guidelines to align with evolving developments in stem cell and organoid research. India has done none of this. Its existing frameworks were built around older conceptions of human tissue, drugs, and biotechnology which are structurally incapable of addressing the organoid question.

This article proceeds in six parts. After the abstract and introduction, Part II explains what human organoids are from a scientific standpoint, establishing the conceptual foundation necessary for legal analysis. Part III surveys India's existing legal and regulatory framework

[1] Hans Clevers, Modeling Development and Disease with Organoids, 165 Cell 1586 (2016); Madeline A. Lancaster & Jürgen A. Knoblich, Organogenesis in a Dish: Modeling Development and Disease Using Organoid Technologies, 345 Science 1247125 (2014).
[2] Inesa Fausch, The Law for Mini-Organ Prototypes in a Dish: Mapping the Legal Status Options for Organoids in Swiss Law, 11 J.L. & Biosciences lsae025 (2024).
[3] Liang-Bin Zhou, Yi-Ting Lei & Xin-Xin Han, Charting Bioethical Frontiers: China's Human Organoid Guidelines in a Global Context, 12 Mil. Med. Res. 64 (2025).

and exposes its critical gaps. Part IV examines judicial interpretations from other jurisdictions, primarily the United States that are instructive for India. Part V explores the practical and contemporary implications of this legal vacuum. Part VI offers concluding recommendations for a sui generis Indian regulatory approach.

Concept of Human organoids

Before law can govern a thing, it must understand what that thing is. Human organoids are 'three-dimensional, self-organized biological structures', developed from human stem cells including "embryonic stem cells (hESCs) and induced pluripotent stem cells (iPSCs)". These miniature tissue models replicate key structural characteristics and physiological functions of their corresponding human organs, making them valuable tools for biomedical research and disease modelling.[4] Unlike traditional cell cultures, which are flat monolayers of cells in a dish, organoids develop architecture. A brain organoid, for instance, will develop layered cortical structures. A kidney organoid will form tubular networks. A liver organoid will generate hepatocyte-like cells capable of metabolic functions.

The significance of this technology cannot be overstated. Organoids are already replacing animal models in pharmaceutical drug-testing, reducing research costs and increasing accuracy. They enable personalised medicine like a patient's own cells can be used to grow an organoid of their tumour, which is then used to test which chemotherapy drug works best, before a single dose is administered to the patient. Organoids are also used in developmental biology research, to understand how organs form during foetal development, and in modelling rare genetic diseases.

The critical legal issue emerges from three specific features of organoids. First, they are derived from human biological material specifically, cells that carry the complete genetic identity of the donor. Second, they can be reproduced, scaled, and commercialised, a single donor's cells could theoretically give rise to organoid lines used in millions of experiments globally. Third, certain organoids most controversially, brain or cerebral organoids have been shown to produce spontaneous neural oscillations, raising the speculative but increasingly serious scientific

[4] Masanori Kataoka et al., Human Brain Organoid Research and Applications: Where and How to Meet Legal Challenges? 21 J. Bioethical Inquiry 603 (2024).

question of whether they could develop rudimentary forms of experience or sentience.[5]

It is precisely these three features, human origin, commercial potential, and potential moral status that make organoids a uniquely difficult object for law to categorise. They are not a human being. They are not merely a chemical compound. They are not exactly like any other biological product previously regulated by law. As one leading journal on organoid law put it in 2024, at present, there is no established legal definition, recognised legal status or existing regulatory framework governing organoids.[6]

India's Existing Legal Landscape and Its gaps

1. The Patents Act, 1970

It is the primary statute governing intellectual property over biological innovations in India. However, it contains several exclusions that create immediate uncertainty for organoids. Section 3(b) bars patents on inventions whose use would be 'contrary to public order or morality' or that 'cause serious prejudice to human, animal or plant life or health or to the environment.'[7] Section 3(j) excludes from patentability "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for the production or propagation of plants and animals."[8]

The question is whether an organoid a human-derived three-dimensional tissue construct qualifies as 'any part' of a human being for the purposes of Section 3(j), thereby making it categorically non-patentable, or whether the significant human ingenuity involved in creating it removes it from this exclusion. Analogously, in the context of 3-D bioprinting a closely related technology legal commentary in India has noted that the naturally occurring patient's cells used to create 3-D printed tissues or organs automatically fall within the scope of" any part thereof" u/s 3(j).[9]

This reasoning, if applied to organoids, would deny patent protection to the organoids themselves, though it may still be possible to patent the method of creating them. This is a

[5] Itzy M. Morales Pantoja et al., Brain Organoids and Organoid Intelligence from Ethical, Legal, and Social Points of View, 6 Front. Artif. Intell. 1307613 (2024).
[6] Fausch, supra note 2.
[7] The Patents Act, No. 39 of 1970, § 3(b), India Code (1970).
[8] The Patents Act, No. 39 of 1970, § 3(j), India Code (1970).
[9] 3-D Bioprinting: Patentability Challenges in India, Asia IP L. (2022).

significant and unresolved ambiguity. If researchers cannot patent organoids, investment in this science in India will be severely chilled. Simultaneously, if organoids are freely patentable, the commercialisation of human biological material without donor consent or benefit-sharing becomes a serious ethical and constitutional concern.

2. The Drugs and Cosmetics Act, 1940

At present, India's regulation of stem cell based products are governed by "the Drugs and Cosmetics Act, 1940". Under this framework, cellular therapy products are classified as drugs and must obtain regulatory approval from "the Central Drugs Standard Control Organisation (CDSCO)" before they can be developed or used.[10] The "ICMR-DBT Guidelines for Stem Cell Research", originally introduced in 2007 and revised periodically, classify stem cell research into three categories - permissible, restricted, and prohibited. The guidelines also require that all eligible research proposals are subjected to be reviewed and approved by an 'Institutional Ethics Committee' before proceeding.[11]

However, neither "the Drugs and Cosmetics Act" nor "the ICMR-DBT guidelines" contemplate organoids as a distinct category. The guidelines focus on stem cells themselves their source, processing, and clinical application not on the three-dimensional organ-like structures that may be grown from them. The "2025 National Guidelines for Stem Cell Research" issued jointly by the ICMR and DBT acknowledge organoid research indirectly, but stop short of providing any governance framework specific to organoids.[12]

This is a critical gap. The drug regulatory framework is designed for substances that are administered to patients. Organoids exist in a space before and beyond that they are research tools, they are platforms, and they are potentially transplantable structures. Treating them as drugs is both over-inclusive and under-inclusive simultaneously.

3. The DPDPA, 2023 and Genomic Privacy

This Act governs the processing of digital personal data. Organoids, however, present a distinctive privacy problem that the DPDPA is not designed to address: the problem of

[10] National and International Regulatory Requirements on Stem Cell Research, 17 Indian J. Health Sci. & Biomed. Res. (KLEU) 16 (2024).
[11] Indian Council of Med. Res. & Dep't of Biotechnol., National Guidelines for Stem Cell Research (2017 rev.).
[12] Indian Council of Med. Res. & Dep't of Biotechnol., National Guidelines for Stem Cell Research (2025).

biological data. An organoid grown from a patient's iPSCs carries that patient's complete genomic information. It is, in a sense, a living repository of their most intimate biological data. Research performed on that organoid and the findings generated could reveal sensitive health information about the donor, including disease predispositions, heritable conditions, and genetic traits.

The DPDPA covers personal data in digital form. It does not address biological material or research findings derived from biological sources. This creates a loophole: a research institution could generate extensive personal health information by studying a patient's organoid without ever technically processing 'digital personal data' within the meaning of the Act. The patient would have no legal remedy under the DPDPA, and no other Indian statute fills this gap.

4. The Human Tissue Gap: No Ownership Framework

India has no dedicated human tissue statute comparable to the "Human Tissue Act, 2004" of the United Kingdom. There's no Indian law that explicitly pertains to the question of whether an individual retains any property interest in biological material removed from their body. The "Transfer of Property Act, 1882" governs the transfer of property, but it does not contemplate biological material as property. "The Indian Contract Act, 1872" governs agreements over property but a patient cannot enter a legally recognised agreement over the use of cells removed from their body because those cells do not have a defined legal status as property under Indian law.

This lacuna is not merely academic. It directly determines whether a patient whose cells are used to grow a commercially successful organoid line has any right to share in the profits, any right to withdraw consent for future use, or any right to know how their biological material is being used. Under the current Indian legal framework, the answer to all three questions is, at best, unclear, and at worst, negative.

Judicial Interpretation: What Courts Have Said (Learnings For India)

"Moore v. Regents of the University of California (1990)"

The most significant judicial decision on the property rights of individuals in their own biological material remains the California Supreme Court's landmark ruling in "Moore v.

Regents of the University of California", decided in 1990.[13] '*John Moore was treated for hairy-cell leukemia at UCLA Medical Centre'*. His physician, without Moore's knowledge, developed a commercially valuable cell line from Moore's excised spleen cells and patented it. When Moore discovered this, he sued for conversion the tort of treating another's property as one's own.

The California Supreme Court, in a four-to-three decision, ruled that Moore did not have any personal property claim over the cell line derived from his bodily material. The court distinguished between Moore's original cells which were naturally occurring and the cell line which was "both factually and legally distinct" from the cells taken from Moore's body, being the product of considerable human ingenuity and skill.[14] The court permitted the claim to proceed on the narrower grounds of breach of fiduciary duty and lack of informed consent but denied any property-based remedy.

The implications of Moore for organoid law are profound. If Moore's reasoning were applied in India and there is no reason it could not be persuasive to an Indian court in the absence of domestic authority a patient whose cells are used to create a commercially successful organoid would have no property claim over it. They would need to rely on informed consent law, which in India is itself inadequately developed for this context.

However, Moore has been widely criticised by scholars and ethicists. A close reading of the dissent in Moore suggests that denying property rights in one's own cells while allowing those cells to be commercially exploited by researchers is morally incoherent.[15] The dissenting justices pointed out that the majority's reasoning essentially strips the patient of rights over their own biological identity while conferring those rights on the institutions that happen to possess the material. This critique is directly relevant to organoid research in India, where institutional power asymmetries between large research hospitals and individual patients are even more pronounced than in the United States.

The Delhi High Court and Posthumous Biological Material (2024)

While not directly concerned with organoids, the Delhi High Court's reasoning in a 2024 case

[13] Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).
[14] Id.
[15] Patenting of Human Genetic Material v. Bioethics: Revisiting the Case of John Moore v. Regents of the University of California, Issues Med. Ethics.

concerning the release of a deceased person's frozen sperm sample to his parents is instructive. The Court accepted the argument that biological material including gametes could be classified as 'property,' likening semen samples to the human corpse or its organs for the purpose of establishing property-like interests. The Court also invoked the Hindu Succession Act to establish that parents, as Class-I legal heirs, had rights over their deceased son's genetic material in the absence of a spouse.[16]

This reasoning, if extended analogically, would suggest that Indian courts are not entirely inhospitable to property-style reasoning over biological material. However, the Delhi High Court's ruling was case-specific and explicitly called on the Ministry of Health to develop clearer legislation on posthumous biological material. It does not constitute binding authority on the ownership of organoids, and its reasoning has not been tested or extended.

The International Society for Stem Cell Research (ISSCR) Guidelines, 2021

While not judicial decisions but the “ISSCR Guidelines of 2021” represent the closest thing to an international consensus framework on stem cell and organoid research ethics. The ISSCR Guidelines require institutional oversight of organoid research, including consideration of the moral status of brain organoids. They recommend that any research involving structures capable of integrated neural activity should be subject to specialised review. India's ICMR-DBT framework does not currently incorporate these standards, though the 2025 National Stem Cell Guidelines appear to move incrementally in this direction.

Practical Implications and Contemporary Issues

1. The Commercialisation Problem

Indian pharmaceutical and biotechnology companies are increasingly investing in organoid technology for drug screening and personalised medicine. This creates a real and immediate commercialisation problem. A company that uses a patient's iPSCs to grow a liver organoid, identifies a profitable drug-testing application, and commercialises the organoid line at scale all without the patient's knowledge or any benefit-sharing arrangement is not currently violating any Indian statute. This is not a hypothetical scenario. It is a foreseeable consequence

[16] Gurvinder Singh & Harbir Kaur v. Union of India, W.P. (C) No. _/2024, at order dated Oct. 2024 (Del. H.C.) (reporting source: LawBeat, Oct. 5, 2024).

of the current regulatory gap.

The commercialisation problem is compounded by the export dimension. Indian research institutions collaborate extensively with international pharmaceutical companies. Organoid lines or the data derived from them could be exported to foreign jurisdictions where they are commercialised, leaving the Indian donor with no legal recourse under either Indian or foreign law. The DPDPA, 2023 contains provisions on cross-border data transfers, but biological material and organoid-derived research findings are not 'data' for this purpose.

2. The Brain Organoid Moral Status Crisis

The most philosophically complex contemporary issue in organoid law is the debate surrounding the moral and legal status of brain organoids. Cerebral organoids have been observed to produce spontaneous neural oscillations patterns of electrical activity resembling those seen in the foetal brain. Researchers and ethicists disagree sharply about the significance of this: some argue that the structural complexity needed for sentience or consciousness is far beyond what current organoids can achieve; others argue that the precautionary principle demands that we do not assume the absence of morally relevant experience.

China's 2025 “Human Organoid Research Ethical Guidelines” a pioneering national governance framework worldwide, addressed this technology directly. The Guidelines adopted a preventive governance model which mandated real-time EEG monitoring of brain organoids to implement complexity caps to prevent the emergence of potentially conscious structures.[17] The ISSCR Guidelines similarly recommend that brain organoid research be subject to heightened ethical review.

India has nothing comparable. The question of whether a brain organoid grown in an Indian laboratory has any legally cognisable moral status or any claim to treatment that minimises potential suffering is entirely unaddressed. This is not merely a philosophical concern. It is a question that will come before Indian regulatory bodies and eventually Indian courts as the science advances.

[17] Asia Pac. Neuroethics Working Grp., Ethics and Regulation of Human Brain Organoid Research (2026).

3. Informed Consent and Donor Rights

The informed consent framework in India, as articulated by the Supreme Court in "Samira Kohli v. Dr. Prabha Manchanda (2008)", establishes that a patient must be given adequate information about a proposed procedure to make a genuine choice.[18] However, this framework was developed in the context of surgical procedures and clinical treatment. It does not contemplate the scenario where a patient's biological material cells taken during a routine biopsy, for instance is later used to create organoids for research or commercial purposes that were not disclosed at the time of initial consent.

The "ICMR National Ethical Guidelines for Biomedical and Health Research (2017)" do address the importance of informed consent in research involving human biological material, and require that consent cover the specific purposes for which material will be used. Nonetheless, these guidelines are not legally enforceable and their enforcement mechanism is weak. A researcher who uses biological material for organoid creation without specific consent for that purpose would face, at most, institutional disciplinary proceedings not legal liability.

4. India's Biotech Competitiveness and the Regulatory Paradox

India faces a genuine regulatory paradox with respect to organoids. On one hand, an absence of clear rules creates legal uncertainty that discourages serious long-term investment by both domestic and foreign biotechnology companies. Investors need to know whether organoid patents will be granted, whether organoid-derived data can be exported, and whether there is any liability exposure from using patient-derived material. The current silence on all these questions is an investment deterrent.

In contrast, premature or overly restrictive regulation modelled, say, on a pharmaceutical approval framework that requires extensive pre-market review could stifle academic and early-stage commercial research before the technology has matured enough to justify such regulatory burden. The challenge for Indian policymakers is to create a framework that is light enough not to suffocate innovation while robust enough to protect patient rights and ethical standards. China's three-tiered governance model distinguishing between low-risk organoid research subject to standard oversight, medium-risk research requiring enhanced review, and high-risk research (particularly brain organoid research with potential for consciousness) requiring

[18] Samira Kohli v. Dr. Prabha Manchanda, (2008) 2 S.C.C. 1 (India).

specialised committee approval offers a useful template for India.

Conclusion

The central argument of this article is simple but urgent: human organoids do not fit neatly into any existing legal category in India, and the consequences of this mis-fit are serious enough to demand legislative attention now, before the science outruns the law completely.

Based on the foregoing analysis, this study proposes several legal reforms for India. Foremost among these is the enactment of a dedicated "Human Biological Material Act" to clearly define the legal status of biological materials obtained from the human body, specify the rights of donors in relation to derivative products such as organoids, and establish an equitable benefit-sharing mechanism where commercial use generates economic value. While the proposed legislation may draw inspiration from the UK "Human Tissue Act, 2004", it should be adapted to India's constitutional framework, particularly the protection of "human dignity and bodily integrity guaranteed under Article 21 of the Constitution".

Second, the Patents Act, 1970 should be amended, or CGPDTM (the patent office) should issue clear guidelines, to address the patentability of organoids and organoid-derived methods. The amendment should clarify that the organoid itself as a human-derived structure is not patentable, but that novel and non-obvious methods of creating, modifying, and using organoids may be patented, provided they meet the inventive step and industrial applicability requirements.

Third, ICMR and DBT should develop a dedicated National Guideline on Organoid Research, modelled on China's 2025 Guidelines, that: (a) classifies organoid research by risk level; (b) mandates specific informed consent for organoid creation and use; (c) establishes protocols for brain organoid research including neurological activity monitoring; and (d) creates an inter disciplinary Organoid Research Review Committee with scientific, legal and bioethics representation.

Fourth, the DPDPA, 2023 should be extended, through subordinate legislation, to cover biological data and organoid-derived health information, ensuring that genomic privacy protections apply to research findings derived from a person's biological material even when those findings are not in digital form at the point of derivation.

Fifth, and most fundamentally, Indian courts and the legislature must engage seriously with the question of the moral status of advanced organoids particularly brain organoids. As the science of organoid intelligence develops, India cannot afford to be caught in the position of having no legal answer to the question of how such entities should be treated. A precautionary, graduated approach acknowledging uncertainty about moral status rather than assuming its absence is both scientifically honest and constitutionally appropriate given India's rich tradition of expansive rights jurisprudence under Article 21.

Human organoids are not going to remain a peripheral curiosity of specialised laboratories. They are going to become central to twenty-first century medicine. The law must grow with the science. India's silence on this question is not a neutral position it is a choice and it is the wrong one.

Bibliography

I. Books, Articles and Journal Publications

- Clevers, Hans, Modeling Development and Disease with Organoids, 165(7) Cell 1586 (2016).

- Lancaster, Madeline A. & Jürgen A. Knoblich, Organogenesis in a Dish: Modeling Development and Disease Using Organoid Technologies, 345(6194) Science 1247125 (2014).

- Kataoka, Masanori et al., Human Brain Organoid Research and Applications: Where and How to Meet Legal Challenges?, 21(4) J. Bioethical Inquiry 603 (2024).

- Morales Pantoja, Itzy M. et al., Brain Organoids and Organoid Intelligence from Ethical, Legal, and Social Points of View (2024).

- Indian Journal of Health Sciences and Biomedical Research KLEU, National and International Regulatory Requirements on Stem Cell Research (2024).

II. Law Review / Legal & Policy Scholarship

- Fausch, Inesa, The Law for Mini-Organ Prototypes in a Dish: Mapping the Legal Status Options for Organoids in Swiss Law (2024).

- Zhou, Liang-Bin, Yi-Ting Lei & Xin-Xin Han, Charting Bioethical Frontiers: China's Human Organoid Guidelines in a Global Context (2025).

- Asia IP Law, 3-D Bioprinting: Patentability Challenges in India (2022).

- Asia Pacific Neuroethics Working Group, Ethics and Regulation of Human Brain Organoid Research (2026).

III. Statutes & Regulatory Instruments (India)

- Patents Act, No. 39 of 1970, § 3(b) (India).

- Patents Act, No. 39 of 1970, § 3(j) (India).

- Indian Council of Med. Res. & Dep't of Biotech., National Guidelines for Stem Cell Research (2007, revised 2017).

- Indian Council of Med. Res. & Dep't of Biotech., National Guidelines for Stem Cell Research (2025).

IV. Case Law (India)

- Gurvinder Singh & Harbir Kaur v. Union of India, Delhi High Court, Oct. 2024 (India).
- Samira Kohli v. Dr. Prabha Manchanda, (2008) 2 S.C.C. 1 (India).

V. Foreign Case Law

- Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).

VI. Reports, Commentaries & Bioethics Sources

- Issues in Medical Ethics, Patenting of Human Genetic Material v Bioethics.