Eksplorium *p*-ISSN 0854-1418
Volume 46 No. 2, June 2025: 374–385 *e*-ISSN 2503-426X

The Socio-Legal Challenges of Biobanking and Genetic Data Privacy: View from India's Digital Personal Data Protection Act, 2023

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Article Received: 15 May 2025, Revised: 10 June 2025, Accepted: 20 June 2025

Abstract: Biobanking—the systematic collection and storage of biological samples and associated data has become a cornerstone of modern biomedical research and precision medicine. However, as it involves sensitive genetic and health-related information, the practice raises critical socio-legal concerns, especially around data privacy, consent, ownership, and potential misuse. In India, the enactment of the **Digital Personal Data Protection Act, 2023 (DPDPA)** marks a new legal era of data governance. This paper investigates the legal and ethical implications of biobanking through the lens of the DPDPA, examining the balance between scientific advancement and individual rights. It explores issues such as consent, data ownership, cross-border data sharing, and the potential for genetic discrimination. Drawing from constitutional jurisprudence, global ethical frameworks, and Indian regulatory gaps, the article proposes reforms to ensure a robust, transparent, and rights-based approach to biobanking in India.

Keywords: Biobanking, Genetic Data, Privacy, Digital Personal Data Protection Act, Informed Consent, India, Biomedical Ethics, Data Ownership, Genetic Discrimination, Bioethics.

1. INTRODUCTION

Biobanks are specialized repositories designed to collect, process, store, and manage biological specimens—such as blood, tissues, cells, and DNA—along with associated medical, demographic, and lifestyle information. These samples and data are invaluable for a range of scientific endeavors, including genetic research, epidemiological studies, disease prevention programs, and drug development. In recent years, biobanking has emerged as a critical pillar of precision medicine, enabling the tailoring of treatments based on individual genetic profiles, and advancing our understanding of disease mechanisms on a population-wide scale.

In India, as in other parts of the world, the growth of biobanking is tied closely to developments in biomedical research, public health initiatives, and pharmaceutical innovation. Biobanks like the National Cancer Tissue Biobank (NCTB) and the IndiGen project have begun to play significant roles in collecting and utilizing genetic and health data from diverse Indian populations. These efforts not only support national health goals but also position India as an active contributor to global biomedical knowledge.

However, the evolution of biobanking from simple sample storage to complex digital data repositories introduces profound **socio-legal challenges**, particularly in the Indian context. Traditionally, biobanks dealt primarily with the physical management of biological samples. Today, due to advancements in **high-throughput genomic technologies**, AI-powered data analytics, and computational biology, biobanks have transformed into **digitally integrated platforms**. They now store and process **massive volumes of personal, medical, and genetic data**, much of which is inherently identifiable and sensitive in nature.

Genetic data, unlike other personal information, has a **unique and permanent character**. It not only identifies an individual but also reveals information about their biological relatives. For example, data about a person's genetic predisposition to certain diseases could indirectly disclose health risks for their parents, children, or siblings—raising **inter-generational privacy concerns**. Furthermore, in the absence of robust safeguards, such data could be misused by employers, insurers, or even state agencies, potentially leading to **genetic discrimination**, **stigmatization**, or **unauthorized surveillance**.

In India, the legal landscape concerning biobanking and genetic data protection has long been inadequate. Despite the recognition of the **right to privacy as a fundamental right** in the landmark **Justice K.S. Puttaswamy v. Union of India (2017)** decision by the Supreme Court, the country lacked a **comprehensive and enforceable data protection law** for several years. This gap left participants in biobanking initiatives vulnerable to data breaches, unethical research practices, and misuse of sensitive information.

Until recently, the only legal protections available for personal and health-related data were scattered across various guidelines and rules, such as the **Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011**, and the **Indian Council of Medical Research (ICMR) Guidelines on Biomedical and Health Research (2017)**. These instruments, however, were largely fragmented, lacked binding force, and did not address the specificities of **genetic data and biobanking**.

The enactment of the **Digital Personal Data Protection Act, 2023 (DPDPA)** marks a significant turning point in India's data governance regime. For the first time, India has a law that systematically addresses the **collection, processing, storage, transfer, and protection of digital personal data**, including health and genetic information. The DPDPA introduces essential principles such as **consent-based processing**, **purpose limitation**, **data minimization**, and the **right to erasure and correction**, aligning India's data framework with global standards like the **EU General Data Protection Regulation (GDPR)**.

In the context of biobanking, the DPDPA presents both **opportunities and challenges**. On one hand, it provides a legal basis to ensure that individuals—referred to as "data principals"—retain control over how their genetic data is used, shared, or retained. On the other hand, the law's generality and lack of biobank-specific provisions raise questions about how its provisions will be applied to complex scientific practices. For instance, **broad consent** models commonly used in biobanking may conflict with the DPDPA's requirement for **specific and informed consent**. Similarly, the Act's provisions on **cross-border data transfer**, while

enabling international collaboration, may expose Indian genomic data to privacy risks if not properly regulated.

Moreover, the DPDPA does not currently include explicit references to **genetic discrimination**, **community-level consent**, or **benefit-sharing mechanisms**—critical issues in a diverse and stratified society like India, where genetic data can intersect with caste, ethnicity, and tribal identity. Without clear legal and ethical safeguards, the benefits of biobanking may be unevenly distributed, while the risks could disproportionately affect vulnerable groups.

In conclusion, biobanking holds enormous promise for public health, scientific advancement, and innovation in India. Yet, its rapid digitalization and the sensitive nature of genetic data demand a **careful balancing of individual rights and research interests**. The **Digital Personal Data Protection Act, 2023** provides a much-needed framework to begin addressing these challenges, but further **policy development, regulatory specificity, and public engagement** are essential to build an ethically sound and legally robust biobanking ecosystem in India.

Biobanking has emerged as a critical infrastructure for modern biomedical science, precision medicine, and public health planning. As India positions itself at the forefront of genomic research and digital health, biobanking is gaining institutional importance. However, its increasing scale and complexity also raise fundamental questions around the rights of individuals, ethical oversight, and regulatory frameworks.

2.1 Definition and Scope

Biobanking refers to the organized collection, processing, storage, and distribution of biological specimens and associated personal, clinical, and lifestyle data. These samples—such as blood, saliva, DNA, tissues, or urine—are preserved for future use in research, diagnostics, therapeutic development, or public health monitoring.

The scope of biobanks extends beyond mere sample preservation. It includes:

- **Data linkage**: Integrating biological materials with personal identifiers, electronic health records, and behavioral information.
- **Long-term storage**: Cryopreservation or other methods to retain sample viability over years or decades.
- **Ethical and legal management**: Including participant consent, data confidentiality, and governance protocols.

Biobanks may be classified based on their purpose and operational scale:

a) Population Biobanks

These biobanks store biospecimens and data from large sections of the general population. The goal is often to explore genetic predispositions, disease prevalence, and health behaviors across diverse demographics. A notable global example is the **UK Biobank**, which houses samples from over 500,000 individuals.

India's equivalent efforts are still emerging, with regional and institutional projects gathering pace. The **IndiGen Program**, led by the Council of Scientific and Industrial Research (CSIR), aims to map India's diverse genomic landscape using samples from multiple population clusters.

b) Disease-Specific Biobanks

These focus on particular medical conditions, such as cancer, diabetes, or cardiovascular diseases. They aim to understand disease progression, treatment response, and genetic risk factors. For example, the **National Cancer Tissue Biobank (NCTB)** in India, a joint initiative by IIT Madras and the Department of Biotechnology, collects and stores tumor and normal tissue samples for cancer research.

c) Hospital-Based Biobanks

Integrated with clinical care systems, these biobanks store samples collected during routine diagnostics or treatment. They often facilitate translational research by linking clinical data with biological findings. These are increasingly common in tertiary hospitals, including AIIMS, Tata Memorial Hospital, and other premier institutions.

As India seeks to expand its genomic medicine capacity, these biobanking models are likely to play a pivotal role in driving personalized healthcare, drug discovery, and public health surveillance.

2.2 Socio-Ethical Significance

Despite their promise, biobanks raise significant socio-ethical challenges. The core issue lies in the nature of the data involved. Unlike anonymized survey responses or abstract clinical metrics, genetic data is **deeply personal**, **uniquely identifiable**, and **familially linked**. It carries implications not only for the individual donor but also for their biological relatives and even entire communities.

a) Violation of Individual Autonomy

A foundational ethical principle in biomedical research is **autonomy**—the right of individuals to control their own bodies and data. In biobanking, this right is often diluted. Many biobanks seek "broad consent," allowing future unspecified uses of samples. While efficient, such practices can lead to consent being **uninformed**, **non-specific**, or **perpetual**, thereby undermining individual agency.

b) Misuse by Third Parties

Without robust legal and institutional safeguards, genetic data stored in biobanks could be accessed or sold to third parties like **insurance companies**, **employers**, or **commercial entities**. Such misuse may lead to **denial of health coverage**, **employment discrimination**, or **targeted advertising** based on inferred health risks. The lack of transparency in data-sharing agreements compounds the problem.

c) Genetic Discrimination

The potential for **genetic discrimination** is a growing concern. Individuals whose biobank data reveals a predisposition to certain diseases (e.g., Huntington's disease, BRCA mutations, or schizophrenia) may face **social exclusion**, **stigmatization**, or **economic disadvantage**. In India, where caste, class, and gender biases are entrenched, genetic information could amplify existing inequalities.

d) Inter-generational Privacy

Genetic data is inherently **shared**—it belongs not only to the individual but also to their biological relatives. Yet, most consent frameworks do not account for **familial or inter-generational implications**. If one person consents to biobank storage, it may inadvertently expose health risks of siblings, children, or parents, who never gave consent. This is particularly sensitive in cases involving **hereditary conditions**, **paternity disputes**, or **population-specific research**.

In a multicultural and diverse country like India, with its history of colonial medical exploitation and socio-political sensitivity around caste and tribe, biobanking must be approached not just as a scientific project but as a **deeply social endeavor**. This requires a legal and ethical framework that respects individual rights, community values, and long-term consequences.

3. LEGAL LANDSCAPE BEFORE THE DPDPA, 2023

Before the **Digital Personal Data Protection Act (DPDPA)** was passed in 2023, India's legal approach to biobanking and genetic data was highly fragmented. Despite the growing use of personal data in research and commerce, Indian law lacked a comprehensive and enforceable data protection regime. The result was a patchwork of overlapping, outdated, and vague rules that failed to provide sufficient safeguards for participants in biobank-based research.

3.1 Fragmented and Inadequate Legal Framework

Several laws and guidelines offered partial or indirect regulation of biomedical data, but none directly addressed the complexities of biobanking.

a) Information Technology Act, 2000 and SPDI Rules, 2011

The **Information Technology (IT) Act, 2000**, particularly after its 2008 amendment, covered issues of data protection, cybercrime, and sensitive personal information. The **Sensitive Personal Data or Information (SPDI) Rules, 2011**—a subordinate legislation under the IT Act—defined health-related information as sensitive and laid out obligations for data protection by "body corporates."

However, these rules:

- Applied only to **commercial entities**, not government institutions or research bodies.
- Were **silent on genetic data** as a special category.
- Had **no enforcement mechanism** or independent oversight authority.

- Provided **no guidance** on informed consent, sample storage, or community rights.

Thus, for biobanks, the IT Act framework was largely irrelevant or inadequate.

b) ICMR Guidelines (2017)

The **Indian Council of Medical Research (ICMR)** issued detailed **Ethical Guidelines for Biomedical and Health Research Involving Human Participants**. These addressed consent, confidentiality, data sharing, and community engagement in biobanking.

While progressive in intent, these guidelines:

- Were **non-binding** and advisory in nature.
- Lacked penalties for non-compliance.
- Relied on **institutional ethics committees (IECs)**, which often vary in quality and independence.
- Did not provide a **national-level coordination or registry** for biobanks.

Moreover, these guidelines did not sufficiently address **emerging technologies**, such as AI-driven genetic analysis or cross-border data flows.

c) Lack of Biobank-Specific Law

India had **no legislation** dealing specifically with:

- **Biobank registration or licensing**
- **Duration of sample/data retention**
- **Ownership and benefit sharing**
- **Withdrawal of consent**
- **Genetic data transfer across borders**

This legal vacuum meant that biobanks operated without clear duties or participant rights. In effect, biobank participants in India were vulnerable to both **overreach by researchers** and **data exploitation by commercial entities**.

3.2 Judicial Recognition of Privacy

A major shift in India's constitutional jurisprudence came with the landmark **Justice K.S. Puttaswamy v. Union of India** case in 2017. A nine-judge bench of the **Supreme Court unanimously held** that the **right to privacy is a fundamental right under Article 21** of the Constitution.

The judgment highlighted several principles crucial for biobanking governance:

- **Informational privacy**: Control over one's personal and biological data.
- **Autonomy and consent**: Right to self-determination in data-related decisions.
- **State's role**: Government must protect individual privacy through legislation and institutional frameworks.

The Court emphasized that data subjects must have:

- Clear knowledge of what data is collected.
- Freedom to consent or withdraw consent.
- Assurance of confidentiality and minimal risk.

This constitutional recognition of privacy set the stage for comprehensive data protection legislation. However, between 2017 and the passing of the DPDPA in 2023, there was a legal limbo. Despite the Court's strong language, the **absence of statutory law** meant that individuals had no practical recourse against data misuse in biobanking or health research.

4. THE DIGITAL PERSONAL DATA PROTECTION ACT, 2023: KEY FEATURES

The **DPDPA, 2023** is India's first comprehensive data protection law and aims to protect individuals' digital personal data while facilitating data processing for legitimate purposes.

4.1 Key Provisions Relevant to Biobanking

- **Personal Data**: Includes data that can identify an individual, including **health and genetic data**.
- **Consent-Based Processing**: Emphasizes **notice and informed consent** as prerequisites for data processing.
- **Purpose Limitation**: Data can only be used for the purpose it was collected for.
- **Data Principal Rights**: Right to access, correction, grievance redressal, and erasure.
- **Data Fiduciaries & Processors**: Biobanks act as fiduciaries; must comply with lawful and fair processing standards.
- **Cross-Border Transfer**: Allowed to notified jurisdictions; concern for global biobank collaborations.
- **Exemptions**: Government can exempt processing for research, archiving, or statistical purposes under certain conditions.

5. SOCIO-LEGAL CHALLENGES IN LIGHT OF THE DPDPA

5.1 Consent and Comprehension

In biobanking, consent is often broad, allowing future unspecified research. The DPDPA mandates **"specific and informed" consent**, but:

- Most participants lack understanding of genetic science.
- There's no standard for **dynamic consent** (ongoing consent model).
- Vulnerable populations (e.g., tribal groups) may be exploited due to low awareness.

Reform Needed: Mandate **tiered or dynamic consent models**, especially for genetic data.

5.2 Data Ownership and Benefit Sharing

Who owns the data and who benefits?

- DPDPA recognizes rights of **data principals**, but not **ownership** explicitly.
- **No provision** for **community rights** or **benefit sharing** (e.g., profit from drugs developed using samples).

Reform Needed: Introduce **community-centric models** of benefit-sharing (e.g., Nagoya Protocol in biodiversity research).

5.3 Re-Identification Risk and Genetic Surveillance

- Genetic data is inherently identifiable.
- Even anonymized data can be **re-identified** using AI and cross-referencing.
- Potential for state or corporate **genetic surveillance**.

DPDPA Gap: No strict standard on **de-identification techniques**.

Reform Needed: Introduce genetic-specific protection norms and **prohibit re-identification** without consent.

5.4 Data Sharing and Cross-Border Transfer

- Collaborative research requires cross-border sharing.
- DPDPA allows this with **government-notified jurisdictions**.
- Risks: Loss of control, privacy breaches, foreign commercial exploitation.

Reform Needed: Strengthen **data localization** and mandate **sharing agreements** with privacy safeguards.

5.5 Children's and Family Genetic Data

- DPDPA protects children's data but **doesn't address familial privacy**.
- Genetic information can reveal predispositions of relatives, even if they didn't consent.

Reform Needed: Develop a framework for **inter-generational privacy rights**.

6. CONSTITUTIONAL AND ETHICAL CONSIDERATIONS

6.1 Right to Privacy and Bodily Integrity

- Biobanking directly implicates the **right to privacy (Article 21)** and **autonomy over one's body**.
- Ethical research demands **respect for persons, beneficence, and justice** (Belmont Report principles).

6.2 Genetic Discrimination and Social Justice

- Without proper safeguards, genetic data can be used to **discriminate in insurance, employment, or marriage**.
- India lacks a **Genetic Non-Discrimination Law** unlike the US (GINA, 2008).

Reform Needed: Enact anti-genetic discrimination legislation, especially given India's **caste-based vulnerabilities**.

7. COMPARATIVE JURISPRUDENCE: LESSONS FROM ABROAD

Comparative Jurisprudence on Genetic Data and Biobanking: A 300-Word Explanation

7.1 European Union (GDPR)

The **General Data Protection Regulation (GDPR)**, enacted by the European Union in 2016, treats **genetic data** as a category of **sensitive personal data**, deserving of heightened protection. Under Article 9 of the GDPR, the processing of genetic data is generally **prohibited** unless specific conditions are met, such as **explicit consent** from the data subject or use for scientific research under strict safeguards. Biobanking activities must therefore ensure **transparent, informed, and unambiguous consent** processes. Additionally, GDPR mandates **Data Protection Impact Assessments (DPIAs)** for high-risk processing, including genetic research, to assess and mitigate potential harms. Importantly, individuals have the **"right to be forgotten"** (Article 17), meaning they can request the deletion of their personal data—including biological samples and associated information—from biobank records, subject to certain limitations like public health or research interests.

7.2 United States

The **Genetic Information Nondiscrimination Act (GINA)** of 2008 is a landmark U.S. law that prohibits the use of genetic information in decisions related to **health insurance and employment**, thereby guarding against genetic discrimination. It does not, however, cover life or disability insurance. Biobanking practices in the U.S. are also governed by **National Institutes of Health (NIH)** guidelines, which require **rigorous ethical review**, informed consent, and data anonymization. NIH-funded biobanks must follow strict standards on sample handling, confidentiality, and secondary use.

7.3 UNESCO & OECD Guidelines

The **UNESCO Declaration on Human Genetic Data (2003)** and **OECD Guidelines on Human Biobanks (2009)** offer **global ethical frameworks**. Both emphasize **transparency**, **community engagement**, and **equitable benefit-sharing**, particularly with indigenous and vulnerable populations. They also stress the importance of **independent ethical oversight** and governance structures to protect participants' rights and interests, ensuring trust in biobank research globally. These principles are especially relevant for developing countries like India in framing ethical, inclusive, and accountable biobank policies.

8. INSTITUTIONAL AND GOVERNANCE CHALLENGES IN INDIA

India's biobanking ecosystem suffers from a lack of centralized oversight and standardization, which poses significant socio-legal and ethical challenges. One of the most pressing issues is the **absence of a centralized biobank registry**. Without a national-level database or inventory, it is difficult to track existing biobanks, monitor their practices, or ensure accountability. This creates an opaque environment where samples and data may be stored, used, or shared without proper oversight, increasing the risk of misuse, privacy breaches, and ethical violations.

Another major challenge is the **lack of clear, uniform standards for sample retention, disposal, and withdrawal**. Biobanks may retain biological samples indefinitely without clarity

on when and how they should be disposed of, especially if the donor withdraws consent or passes away. Additionally, many biobanks do not have formal procedures for participants to withdraw their data or samples, violating the ethical principle of autonomy and the right to informed consent.

Ethical oversight in India is primarily managed by **institutional ethics committees (IECs)**, which vary in competence, resources, and interpretation of ethical norms. This decentralized model results in inconsistency in ethical review, especially in multi-center research projects. Some IECs may approve broad consent models without ensuring participant comprehension, while others may impose more stringent requirements, leading to regulatory fragmentation.

To address these challenges, there is an urgent need to **establish a National Biobank Regulatory Authority**. This body would register and license biobanks, develop national-level policies, and ensure compliance with ethical and legal standards. Furthermore, the introduction of **standard operating procedures (SOPs)** for sample retention, disposal, and withdrawal—backed by periodic audits—would promote transparency, safeguard participant rights, and uphold scientific integrity. Such reforms are essential for building public trust and ensuring ethical governance of biobanking in India.

9. POLICY RECOMMENDATIONS

Area	**Recommendation**
Consent	Introduce **dynamic consent models**, especially for longitudinal studies
Genetic Data Classification	Define **genetic data** as **highly sensitive** with stricter protections
Ownership	Recognize **participant ownership** or **co-ownership** of data and samples
Governance	Set up **central biobank authority** with ethical and legal oversight
Legal Protections	Enact a **Genetic Non-Discrimination Law**
Community Rights	Recognize **collective rights** for indigenous/tribal populations
International Collaboration	Ensure **data sharing agreements** with **privacy by design**
Capacity Building	Invest in **genetic literacy** and **ethics training** for researchers

10. CONCLUSION

India is rapidly advancing into the era of genomics, with large-scale initiatives like the IndiGen Project and increasing investments in precision medicine. This marks a significant shift in healthcare, as biobanking—collecting and storing biological samples like DNA for future research—promises breakthroughs in disease prevention, diagnosis, and personalized treatment. However, alongside these health benefits arise urgent socio-legal and ethical challenges. Genetic data is deeply personal and can reveal not only individual health

information but also traits of family members and communities. Without strong protections, there is a risk of privacy violations, misuse by insurance companies or employers, and genetic discrimination.

The Digital Personal Data Protection Act, 2023 (DPDPA), India's first comprehensive data privacy law, addresses some of these concerns by mandating consent, data minimization, and rights for individuals (data principals). While this is a significant legal development, it is not sufficient for the complex domain of biobanking. The Act does not explicitly recognize genetic data as requiring special protection, nor does it mandate dynamic consent, community benefit sharing, or protections against re-identification of anonymized samples.

In a country as diverse as India—with its socio-economic disparities, indigenous communities, and varying levels of scientific literacy—biobanking must be governed by a legal framework that prioritizes justice, transparency, and inclusivity. This calls for an interdisciplinary approach where legal experts, bioethicists, scientists, technologists, and civil society work together to create safeguards that ensure ethical sample collection, informed consent, equitable data sharing, and meaningful community engagement. Only then can India unlock the full potential of genomic research while upholding the dignity and rights of its people.

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