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ARTICLE

Genomic Security in the Criminal Policies of the BRICS Countries

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Abstract. This article is devoted to the legislative regulation, court practice, and criminal policy in the field of genomic security within the jurisdiction of the BRICS countries. Researchers examine China's experience with national legal regulation on matters related to genomics, the legal practices regarding genomic security in India, and the legal experience with genetic regulation of South Africa. For the longest time, the Chinese model of legal regulation had remained in its infancy; however, the high-profile case of a biologist named He Jiankui, who genetically edited the human genome, raised ethical issues that necessitated urgent legislative settlement. As a result, amendments were introduced to the criminal and civil codes and stricter state control was established over the research activities of scientists and the licensing of clinical trials. In South Africa, for instance, tribal genomic sovereignty is protected by local laws. Nevertheless, the free circulation of genetic data is a cause for concern, licensing control by the South African government is not adequately developed, and there is a lack of sufficient knowledge and training among scientists.

Keywords: BRICS; ethics; legal regulation; security; human rights; criminal policy; biotechnology; genome; DNA; gene editing; CRISPR; reproductive medicine; genomic.

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Introduction

In light of the significant relevance of scientific studies on the human genome and their real-world applications in medicine, forensics, agriculture, and other fields, in recent years there have been active requests arising in this area regarding the regulation of legal, ethical and moral issues, including pressing issues of biosafety and the genomic sovereignty of entire nations.

Experimentation with human genes and the radical invasion of the human genome are not considered acceptable in the world today, as they are still not fully aligned with international and national norms, as well as professional ethical standards.[1] Beyond the uncertainties in the legal framework for biosafety and the chaotic use of genetic technologies by private individuals, this state of affairs is attributed to the subsequent irreversible reactions resulting from "genetic enhancement" and "genome editing." These reactions can include unintentional or deliberate changes to the genetic code, which are subsequently transmitted to future generations who in turn have not consented to such consequences.

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[1] Li, J.-r., et al. (2019). Experiments that Led to the First Gene-Edited Babies: The Ethical Failings and the Urgent Need for Better Governance. *Journal of Zhejiang University Science, 20*(1), 32–38.

More than five years have passed since the heated debate surrounding the first engineered babies born in China distracted the entire community from the real benefits of gene editing technologies that could make a real difference in the lives of adults with their serious medical conditions. Some fifty experimental studies are currently being carried out worldwide on human volunteers whose genes are being edited to treat diseases ranging from cancer to HIV and blood diseases (such as sickle-cell disease), forty of these using the CRISPR (Clustered Interspaced Short Palindromic Repeats) or "genetic scissors" technology.[2]

International organizations and nongovernmental scientific associations agree that there is an urgent need for an effective ethical and legal framework aimed specifically at regulating research in the field of genome editing. Over twenty countries now explicitly prohibit germline modification in human reproduction in their legislation, including the United Kingdom (UK), Australia, Germany, France, Netherlands, Belgium, Japan, Canada, Brazil, and South Korea. The BRICS countries, led by China, Russia, and India, are setting an important vector in this direction.

Our empirical basis for this study is the current regulations and ethical standards for genetic biotechnology in the Russian Federation, as well as in several other BRICS countries such as China, India, and South Africa. Techniques of knowledge and data collection, such as the formal-logical method, systematic analysis, statistical techniques, legal-technical, and jurisprudential analysis of the texts of laws and jurisprudence, form the methodological basis of the work. The study also makes use of private scientific methods, such as empirical description, comparative legal method, methods of exegetics and hermeneutics, structural and functional methods, etc.

As for domestic legislation, some states expressly prohibit germline editing through criminal liability, others prohibit it through administrative sanctions, and still others regulate this area through non-binding guidelines.[3] It should be noted that genome editing for research purposes is permitted in the United States and European countries but artificially produced embryos must be destroyed after the experiment, i.e., it is forbidden to implant them for a woman to carry to term.

The Chinese approach to human genome editing is the most liberal approach in all of Southeast Asia, particularly because there is still no mandatory authorization required for genetic diagnosis, although other forms of genetic manipulations in the management of genetic resources are strictly licensed.[4]

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[2] Regalado, A. (2023, March 7). Forget Designer Babies. Here's How CRISPR Is Really Changing Lives: The Gene-Editing Tool Is Being Tested in People, and the First Treatment Could Be Approved This Year. *MIT Technology Review*. https://www.technologyreview.com/2023/03/07/1069475/forget-designer-babies-heres-how-crispr-is-really-changing-lives/

[3] Yotova, R. (2020). Regulating Genome Editing under International Human Rights Law. *International & Comparative Law Quarterly, 69*(3), 653–684.

[4] Trikoz, E. (2021). Criminal Law Codification of the Norms of Genomic Law in the EU and BRICS Countries. In *XI International Congress of Comparative Law "Emergency Situations: Problems of Legal Regulation in Modern Society"* (p. 6). http://dx.doi.org/10.2139/ssrn.4126519

1. China's Experience with National Legal Regulation in the Field of Genomics

The "Made in China 2025" strategy document sets ambitious goals for China to become a global leader in genetic technology production, with an emphasis on biomedicine and the development of high-performance medical technologies. In January 2022, the Ministry of Commerce and the National Development and Reform Commission issued a general opinion on liberalizing market access in the southern metropolitan area of Shenzhen as part of efforts to further promote reform and openness in the Guangdong-Hong Kong-Macao Greater Bay Area. The document calls for easing market access restrictions for pharmaceutical drugs and medical devices, as well as streamlining permitting processes and access services for human genetic resources.

Over the past decade, there has been impressive financial support for genetic and genomic development in China, both at the government and commercial company level.[5] The "Thousand Talents Plan" or *Qianren Jihua* is considered to be the leading scientific program of the central government of the People's Republic of China (PRC). With the involvement of almost every government agency in China, this program is the most prestigious and influential government science program in the world. *Qianren Jihua*'s overall aim is to promote financial and specific scientific areas, such as the genetics industry and biotechnology in general, as these are considered of paramount and strategic importance by the Chinese government.[6]

One factor that has contributed to the increased attention in this area has been the pioneering yet controversial experiment of Chinese scientist, He Jiankui (贺建奎; born 1984), who by coincidence and talent had been invited to the Chinese government's aforementioned program. This associate professor with the Southern University of Science and Technology publicly announced in November 2018 that he had previously conducted a genetic experiment in his Shenzhen research laboratory, secretly and without a license, to create the world's first children with an artificially altered genome-DNA. This DNA was altered to prevent it from contracting HIV (the "designer babies" effect) by applying the revolutionary "genetic scissors" technology (CRISPR/Cas9). A third child was born the following year using this method.

He Jiankui took advantage of China's lack of an explicit ban on editing a viable human embryo to carry out a risky experiment without expecting to be prosecuted by the authorities. He Jiankui's manuscript shows how he ignored ethical and scientific norms in creating the gene-edited twins Lulu and Nana.[7] And predictably,

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[5] National Science Board. (2012). *Science and Engineering Indicators*. National Science Foundation. http://www.nsf.gov/statistics/seind12/pdf/seind12.pdf

[6] Jing-Bao, N. (2018, December 8). *He Jiankui's Genetic Misadventure: Why Him? Why China?* The Hastings Center. https://www.thehastingscenter.org/jiankuis-genetic-misadventure-china/

[7] Regalado, A. (2019, December 3). China's CRISPR Babies: Read Exclusive Excerpts from the Unseen Original Research – He Jiankui's Manuscript Shows How He Ignored Ethical and Scientific Norms in Cre-

his act was universally condemned not only by Chinese government agencies and international organizations, but also by the scientific community around the world, including experimental geneticists and bioethicists.[8]

One year later, in December 2019, a daring Chinese biophysicist was sentenced by the Nanshan District People's Court of Shenzhen to three years in prison and fined RMB 3 million for illegally editing the genes of three human embryos intended to be reproduced in the womb of a biological mother, which resulted in the birth of three genetically modified babies. The court said in its verdict that researcher He Jiankui, "in the pursuit of personal fame and gain," had "deliberately violated" the country's medical regulations and "rashly applied gene editing technology to human assisted reproductive medicine." He Jiankui's research was illegal because it had violated regulations that had been in place for more than fifteen years, prohibiting unethical or immoral research on the human genome. Two other scientists from two medical institutes in Guangdong Province – Zhang Renli and Qin Jinzhou – were also sentenced to two and a half years in prison, respectively, and fined for illegal gene editing in the field of assisted reproductive medicine.

Still, the field of human genome editing in China remains largely unregulated in the form of a comprehensive law. In the 1990s and 2010s, China progressively strengthened legislation on genomic research, the handling of genetic information, and the operation of genetic data biobanks. The "Reproductive Technology Act" prohibits the use of embryos for commercial goals. The "Maternal and Child Health Protection Law" 1995 regulates the conduct of genetic tests, which does not require authorization for genetic diagnosis. However, these tests can be only performed by a physician who is licensed by the Ministry of Health of the PRC to carry out genetic tests.

In 1998, the State Council adopted "Interim Measures for the Management of Human Genetic Resources." Secondary legislation has also been used, most notably the 2003 Ethical Guiding Principles for Research on Human Embryonic Stem Cells, which sets out a detailed procedure for conducting such research. For example, artificially created embryos can only be studied for fourteen days and cannot subsequently be implanted into the human body. It also established the principle of free and informed consent. In 2008, China established its first independent ethics committee at the Shanghai Clinical Research Centre, which is guided by the World Health Organization's (WHO) "Principles of Conduct for Ethics Committees Reviewing Biomedical Research" and aims to protect the rights of patients involved in clinical research and manipulation.

Under the auspices of the Ministry of Science and Technology of the State Council of the People's Republic of China, the "Guidelines for the Collection, Trade, Export,

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ating the Gene-Edited Twins Lulu and Nana. *MIT Technology Review*. https://www.technologyreview.com/2019/12/03/131752/chinas-crispr-babies-read-exclusive-excerpts-he-jiankui-paper/

[8] Krimsky, S. (2019). Ten Ways in Which He Jiankui Violated Ethics. *Nat Biotechnology, 37*(1), 19–20.

and Export of Genetic Resources" were approved in 2015, and the "Regulation on the Procedure for Review and Approval of Optimization of Human Genetic Resources" came into force in 2017. Following the sensational case of He Jiankui, the Chinese Ministry of Science initiated a special review of the administrative management of licenses issued for the use of human genetic resources in 2018.

On November 29, 2018, the China's Vice Minister of Science and Technology called for the suspension of all work at He's lab, while the Minister of Industry and Information Technology announced a "zero tolerance" policy and banned He Jiankui from competing for a government award for which he had previously been nominated.[9] The China's Ministry of Education sent out notices to self-check gene-editing research in all universities and called for stricter ethics control in the area of research and "monitoring of research related to gene-editing technology."[10]

In early 2019, China's President Xi Jinping called for stricter regulation of gene editing through the implementation of new legislation, and China's State Council announced new regulations on "high-risk" technologies and the establishment of a National Medical Ethics Committee to supervise high-risk clinical trials and samples.[11]

Nevertheless, there has long been no formal criminal law prohibiting DNA editing of viable embryos in China. The government qualified CRISPR technology as a medical technology, not a medicine, so no central government approval was required. Even in the case of embryo research, it was sufficient to obtain approval from the ethics committee of the hospital or IVF clinic to ensure that patients gave informed consent and were not faced with unnecessary risks. This is why such research flourished in China, with twelve medical trials using CRISPR registered, surpassing the number of such trials carried out in the rest of the world at the time.

It was these legal gaps that were exploited by He Jiankui, a biotechnologist and geneticist. The implications of his semi-legal experiment were so significant that they led to amendments to the draft Civil Code and an expansive interpretation of the current Criminal Code of China. Consequently, it was proposed that human genes and human embryos also be included in the section of the Civil Code pertaining to the protection of individual rights. Thus, any experimentation with genes in adults or embryos that threatens public health or is contrary to ethical rules, respectively, could be considered a violation of fundamental human rights.[12]

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[9] Regalado, A. (2018, November 26). The Chinese Scientist Who Claims He Made CRISPR Babies Is Under Investigation. *MIT Technology Review*. https://www.technologyreview.com/2018/11/26/138957/the-chinese-scientist-who-claims-he-made-crispr-babies-has-been-suspended-without-pay/

[10] Yanan, W., & Fu, T. (2019, February 27). China Drafts Rules on Biotech after Gene-Editing Scandal. *Associated Press*. https://www.apnews.com/47aa8ffa382c4ae19eb6ec202f93ddf8

[11] Qiu, J. (2019, March 5). *China Creating National Medical Ethics Committee to Oversee High-Risk Clinical Trials*. STAT. https://www.statnews.com/2019/03/05/china-creating-national-medical-ethics-committee

[12] Cyranoski, D. (2019, May 20). China Set to Introduce Gene-Editing Regulation Following CRISPR-Baby Furore. *Nature*. https://www.nature.com/articles/d41586-019-01580-1

Most importantly, the recently adopted PRC National Regulations on the Management of Human Genetic Resources, 2019 (hereinafter Regulation) aims to strengthen the protection of genetic data and related human biomaterials and tighten the mechanism for regulating and monitoring their proper use.[13] The relevance of this regulation stems from the fact that pharmaceutical companies in China collect large amounts of genetic material for the purpose of drug trials and other research. Incidentally, it was the Chinese company SiBiono GeneTech Co. that developed the world's first commercial gene therapy product, Gendicine®, which was approved by Chinese regulators in 2003 for the treatment of head and neck malignancies with p53 gene mutations.[14]

The aforementioned document defines "genetic resources" as the relevant genetic material (human organs, tissues, and cells containing genes) and genetic information (data that have been obtained through genetic research). The legal status of 'genetic banks' is determined, and they are subject to a number of requirements, including a legal entity status, approved ethical rules for the use of genetic material, and an official license, the absence of which can entail both administrative and criminal liability, etc.

According to Article 4 of the regulation in question, the Ministry of Science and Technology of the State Council of the People's Republic of China has the main authority for regulating genomic research. This body is responsible for organizing research on human genetic resources in China as well as developing specific methods for declaring and implementing a registration system for human genetic materials (Art. 5).

This Regulation also contains the following important points:

1. The Chinese State is responsible for the rational use of human genetic resources in scientific research, diagnostic and therapeutic activities, and the development of the biomedical industry (Art. 6).
2. The collection, storage, use, and transfer of human genetic material by foreign individuals and organizations is prohibited (Art. 7).
3. The collection, storage, or use of human genetic material and genetic information must not endanger national security, public health, or the public interest (Art 8).
4. These activities must comply with ethical principles and approved standards, respecting the patient's right to privacy and the right to prior informed consent (Art. 9).
5. The commercial use of human genetic material is prohibited (Art. 10).

Moreover, it is important to note that the Ministry of Science and Technology has the authority to stop the activities of the offender, confiscate illegally collected,

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[13] National Regulations of the People's Republic of China on the Management of Human Genetic Resources (adopted at the 41st Executive Meeting of the State Council on March 20, 2019, are hereby promulgated and shall come into force on July 1, 2019). The State Council of the People's Republic of China. http://www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm. (In Chinese).

[14] Melnikova, E., et al. (2019). International Practices of Registration and Use of Drugs for Gene Therapy in Clinical Practice. *Antibiotics and Chemotherapy, 64*(1-2), 61.

illegally stored, or illegally used genetic materials, as well as impose fines for violation of the articles of the Regulation in question (Arts. 36–43).

In April 2020, the Standing Committee of the National People's Congress considered a new draft of the Biosecurity Law,[15] which aims to introduce a separate chapter on biosecurity. The draft law proposes a specific chapter on the management of human genetic resources. It would provide for stricter administrative penalties for violations of regulations governing the management of human genetic resources.

In the PRC today, genomic research activities are carried out by research and scientific centers, educational institutions, and medical facilities. However, they are carried out under the direct support of the support and subject to governmental control. The PRC has three of the largest institutions working with large genomic databases and biobanks. They are the Chinese National Human Genome Centre in Shanghai (South Centre), the Chinese National Human Genome Centre in Beijing (North Centre), and the Beijing Institute of Genomics (Shenzhen).[16] In 2021, for example, it was revealed that the All-China Genetic Company, which sells prenatal tests around the world, developed them in collaboration with the Chinese military and used them to collect genetic data from millions of women, ostensibly for subsequent large-scale studies of population traits. This genetic data, which is collected from both within and outside China, is stored in the PRC government-funded gene database, one of the largest in the world.[17]

However, those and other organizations must be provided with the necessary certified equipment, and the research they carry out has to comply with an approved quality control system. Furthermore, strict records must be kept of the research carried out and be regularly sent to the State Council of China. All genomic research organizations must also adhere to an approved list of procedures and services, and all new methods of genomic research are required to undergo compulsory registration. In the cases of ethical problems or high risk, these methods are subjected to review by the competent state organizations.[18]

In the autumn of 2022, it became known that the Chinese authorities were collecting DNA samples throughout the Tibetan Autonomous Region, including from kindergarten children, without the explicit consent of their parents, as part of a campaign to "solve crimes." Systematic DNA collection began back in 2019 as part of the "Three Greats" initiative (inspection, investigation, and mediation) designed

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[15] Biosafety Law of the People's Republic of China (Draft). (2020). http://law.foodmate.net/file/upload/202005/01/093552211434922.pdf. (In Chinese).

[16] Yoshizawa, G., et al. (2014). ELSI Practices in Genomic Research in East Asia: Implications for Research Collaboration and Public Participation. *Genome Medicine, 6*(5). https://doi.org/10.1186/gm556

[17] Needham, K., & Baldwin, C. (2021, July 7). Special Report: China's Gene Giant Harvests Data from Millions of Women. *Reuters*. https://www.reuters.com/article/us-health-china-bgi-dna-idUSKCN2ED1A6

[18] Vasiliev, S. (2020). Analysis of Administrative and Legal Regulation of Genomic Medicine in China. *Bulletin of South Ural State University, Law Series*, *20*(3), 112. (In Russian).

to strengthen China's intense grassroots policing system. State tenders were even issued for the establishment of local DNA databases in 2019.

Although several human rights activists have argued that the police had no credible evidence of criminal behavior to justify such collection, and people were not given the option to refuse to participate in the collection of genetic data, which is a serious human rights violation as such a measure "cannot be justified as necessary or proportionate."[19]

Despite the fact that Chinese law restricts the collection of DNA samples to those individuals linked to a specific criminal case, authorities frequently conduct campaigns to collect biometric information and DNA data from ordinary citizens for an unspecified need to solve crimes. Nevertheless, any forcible collection or taking of blood samples without informed, meaningful, and voluntary consent and then the use of such data by the state is "a serious infringement of the right to privacy, human dignity, and physical freedom."[20]

2. National Legal Regulation of Genomic Security in India

India has a number of laws governing clinical research, including genetic research: the Drugs and Cosmetics Act, 1940; the Medical Council of India Act, 1956; the Guidelines for Exchange of Biological Material, 1997; the Right to Information Act, 2005; and others.

The Indian Penal Code, 1860, in several articles under its Special Part makes direct or indirect reference to the use of DNA technology, particularly in offenses such as culpable homicide (sec. 299), murder (sec. 300), culpable homicide by causing the death of a person other than the person whose death was interned (sec. 301), causing death by negligence (sec. 304-A), dowry death (sec. 304-B), abetment of suicide (sec. 306), causing miscarriage (sec. 312), causing miscarriage, injuries to unborn child, infant's exposure or concealment after birth (sec. 313–315), rape (sec. 375), intercourse of man with wife during separation (sec. 376A), intercourse by a public servant with a women in custody (sec. 376B), intercourse by a superintendent of a jail or remand home (sec. 376C), by management staff of hospital (sec. 376D), and adultery (sec. 497).[21]

Yet, such legal acts are unclear and incomplete with regard to the identification of persons based on genetic data (e.g., for the purposes of identifying victims of natural

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[19] Human Rights Watch. (2022, November 5). *China: New Evidence of Mass DNA Collection in Tibet*. https://www.hrw.org/news/2022/09/05/china-new-evidence-mass-dna-collection-tibet

[20] Davidson, H. (2022, September 5). China Collecting DNA Samples from Across Tibet, Says Rights Group. *The Guardian*. https://www.theguardian.com/world/2022/sep/05/china-collecting-dna-samples-from-across-tibet-says-rights-group

[21] Krasheninnikova, N., & Trikoz, E. (2022). Criminal Protection of Women's Rights in India: History and Modernity. *Bulletin of St. Petersburg University, Law, 13*(1), 230–245. (In Russian).

disasters, accidents, or missing persons, etc.). In 2016, therefore, the Department of Biotechnology, Government of India, initiated a special bill on the "Use and Regulation of DNA-based Technology in Civil and Criminal Proceedings, Identification of Missing Persons, and Human Remains Bill" and sent it to the Law Commission for approval.

The drafters of the bill argued that DNA profiling technology, which based on proven scientific principles, is highly effective for maintaining social order and stability in society, protecting against rampant crime and allowing the justice system to identify criminals by their genotype. DNA technology is being actively used in solving crimes and identifying unidentified corpses in certain types of civil disputes (succession, inheritance, paternity search), for medical purposes, etc.[22]

Multiple court cases have confirmed that the DNA test yields 99.99 percent accurate results and should be perceived as an objective scientific test that is almost impossible to disprove.[23] Another case highlighted that genetic testing conducted by a party to a criminal case without a doubt constitutes corroborating supporting evidence for his or position.[24] DNA testing has steadily become an established part of criminal proceedings, and the admissibility of test results has become common practice in court.[25] The Supreme Court of India has repeatedly upheld the admissibility of DNA testing as evidence in the legal proceedings both independently and in conjunction with other evidence; however, the Court has clarified that when there is a discrepancy between ocular evidence and medical evidence (expert-DNA evidence), the former takes precedence.[26]

The very first use of DNA testing in Indian courts occurred in 1988 in Kerala in the paternity case[27] of *Kunhiraman v. Manoj*, just a year after the first use of genetic testing in US courts.

The Criminal Procedure Code, 1973 contains an indirect provision for DNA testing, which has long been used in complex investigative and judicial situations. For example, Article 53 of the Code provides for the examination of an accused person by a medical practitioner at the request of a police officer or investigator who has reasonable grounds to believe that the examination will yield relevant evidence of a crime. Section 54 provides for examination of an arrested person by a registered medical practitioner at the request of the arrested person.

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[22] Mishra, B. (2007). DNA & Indian Legal System. *The Shillong Times*.

[23] *Veeran v. Veeravarmalle & Anr.*, AIR 2009 Mad. 64; *Harjinder Kaur v. State of Punjab & Ors.*, (2) RCR (Criminal) 146 (2013).

[24] *Simpson v. Collinson* (1964) 1 All ER 262.

[25] Singh, S. Ch. (2011). DNA Profiling and the Forensic Use of DNA Evidence in Criminal Proceedings. *Journal of the Indian Law Institute, 53*.

[26] *State v. Sughar Singh*, 1978 Cr LJ 141: AIR 1978 SC 191; *Surinder Singh v. State of UP*, 2003 Cri LJ 4446; *State v. Suraj Singh Yadav*, 2004 Cri LJ 2132 (All).

[27] *Kunhiraman v. Manoj*, 1991(2) KLT 190 at 195.

In the case of *D.J. Vaghela v. Kantibai Jethabai*, 1985, the High Court held that the taking of blood, semen, saliva, urine, and other samples under Section 53 of the Code of Criminal Procedure did not violate Article 20(3) of the Constitution which allows protection against self-incrimination under Sections 156 and 174 of the Code of Criminal Procedure.

The Code of Criminal Procedure (Amendment) Act, 2005 added a new Section 53-A to this code, under which a rape accused may be examined by a medical practitioner for the purpose of taking bodily samples from the accused for further genetic analysis and DNA testing.[28]

Section 27(1)15 of the Prevention of Terrorism Act, 2002 states that the investigating officer must make a written request to the court for permission to take samples of blood, saliva, semen, hair, handwriting, fingerprints, footprints or voice of an accused who is reasonably suspected of involvement in a terrorist offense. In that case, the court may order such samples to be given by the accused to a police officer, either through a medical practitioner or otherwise, whichever is appropriate.[29]

In India, barriers to realizing the full potential of DNA evidence include a lack of clear communication between law enforcement agencies and court and laboratory personnel, limited resources in carrying out research on human DNA, and the use of incompatible systems for genetic testing. Corruption, falsification of court records, false results as evidence, and most importantly, the political authority of the accused, as highlighted in the high-profile Madhumita Shukla case of Uttar Pradesh [Madhumita case, 2007], additionally remain major barriers.

After examining various court orders and constitutional provisions, the Law Commission of India published its 2017 annual report titled "The DNA Based Technology (Use and Regulation) Bill." Two years later, the Minister of Science and Technology of India introduced the "DNA Technology (Use and Application) Regulation Bill, 2019" in the Lok Sabha. It provides for mandatory accreditation and regulation of DNA laboratories under the *aegis* of the DNA Regulatory Board, reliability and enhanced protection of DNA test results against misuse or misuse. The law proposes the establishment of national and regional genetic data banks, including for the purposes of forensic DNA-based investigations and forensic analysis and the identification of missing persons, victims, offenders, suspects, missing persons, and unknown deceased persons. The proposed legislation has prompted the development of a single set of ethical guidelines for all laboratories involved in DNA testing.[30] The

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[28] Kumar, S. (2018). *Legal Status of Human Genetic Material – A Study Relating to Human DNA its Ethical Problems and Law* (p. 136). Rawat Prakashan.

[29] Sati, M. (2016, February 11). Evidentiary Value of Forensic Report in Indian Courts. *Scholarticles*. https://scholarticles.wordpress.com/2016/02/11/ms1/

[30] Dhillon, M., et al. (2021). The DNA Technology (Use and Application) Regulation Bill, 2019: A Critical Analysis. *ILI Law Review*, Winter Issue, 278–301.

Digital Personal Data Privacy Bill was also recently passed, which eliminates the distinction between sensitive personal data and general personal data.

In January 2022, after the DNA Bill was introduced in the Upper House, the Directorate of Forensic Science Services (DFSS), which comes under the Ministry of Home Affairs (MHA), issued guidelines and recommendations for collecting forensic evidence in sexual harassment cases and set up a state-of-the-art DNA analysis laboratory, the Central Forensic Sciences Laboratory, in Chandigarh. Following this, in April 2022, the Criminal Procedure (Identification) Bill was enacted. This Bill, which seeks to empower investigators to collect biometric details of prisoners, was passed despite strong protests from the opposition, which saw the law as a precursor to a police state. The law allows police to collect a variety of biometric data on inmates, including iris and retinal scans, fingerprints, palm prints, footprints, and photographs; other physical and biological samples; and even behavioral traits such as handwriting samples and signatures. By using the term "prisoners" it is generally meant all those who have been arrested, detained, convicted, or any person sent under the direction of a judicial or executive magistrate – in effect, "any person involved in any crime."

Ironically, almost a century later, the previous British Identification of Prisoners Act 1920, has been repealed, and in its place the Indian government introduced a law even more intrusive on personal data and with fewer checks and balances. For instance, the Criminal Procedure Identification Act, 2022, that repealed the 1920 Act, allows personal data records of "inmates" to be kept for seventy-five years and allows the National Crime Records Bureau to hand over personal data to "any law enforcement agency." This violates the fundamentally recognized data protection best practices, including the principle of "purpose limitation." And yet the refusal of an inmate to provide a police officer with his biometric data and samples would now be an offense under Section 186 of the Indian Penal Code, i.e., "obstructing a public servant in discharge of public functions." This is almost reminiscent of the post-pandemic and external threat era methods of biopolitics on the part of state authorities.

3. Legal Experience of South Africa with Genetic Regulation

In South Africa's multicultural and multilingual society, different perspectives on the use of biological materials prevail, as local culture attaches great importance to heritage and self-identity, which are passed down through generations in local tribal communities. The South African health care system therefore emphasizes that a patient's decision to participate in clinical testing should also be obtained from his or her family and tribal community. For example, the South African San Institute has developed a separate "Code of Research Ethics" that incorporates five principles from the San worldview, namely respect, honesty, care, justice, and fairness.

These principles are expected to be followed by geneticists and other medical researchers while also accommodating the conventional principles of clinical ethics and due respect to San tribal culture.[31] On the other hand, the South African Constitutional Court has repeatedly stressed that constitutional values should be deciphered through the prism of the "Ubuntu philosophy."[32]

Culturally, many ethnic groups in South Africa view family or community as central, but respect individual choice. Thus, the most important decisions are necessarily reached after consultation with the family or community. The South African specificity of informed consent for DNA testing is discussed in the DoH's guidelines on Ethics in Health Research: Principles, Processes, and Structures, 2015. Respect for the people of the Ubuntu tribal community necessitates discussion of decisions about participation in genetic testing and sharing and consenting to genomic data with family members, as well as the secondary use of such personal data and gene samples for potentially useful research. However, it is characteristic of Africa that the majority of research scientists and patient clients do not have sufficient practical and professional experience in the genomic ethics associated with DNA and exome sequencing studies. Obtaining data on genotypes and phenotypes as well as information on an individual's lineage should be monitored more closely in order to avoid identifying individuals and revealing their identities, families, or tribal communities.[33]

The South African Constitution guarantees autonomy and self-determination: the right to life, dignity, psychological and physical integrity, security and control over one's body, and control over reproductive decisions. Article 12(2)(c) stipulates that "no one shall be subjected to medical or scientific experimentation without their informed consent."[34]

Article 9(3) and (4) of the Constitution prohibit direct or indirect discrimination on one or more grounds, some of which are listed in the article itself (open list). The Promotion of Equality and Prevention of Unfair Discrimination Act, 2000 was enacted, which gives effect to the constitutional equality provision. In the case of indirect discrimination, genetic abnormalities may be attributable to a particular ethnicity or even race. The sickle cell anemia is commonly found in individuals of African descent.

Article 14(d) of the Constitution enshrines a "right to know nothing and to have no information" of a personal nature in the event of breach of confidentiality of communications, which protects the confidentiality of any communication between a person undergoing genetic testing and their physician regarding their genetic result.

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[31] Schroeder, D., Chatfield, K., Singh, M., Chennells, R., & Herissone-Kelly, P. (2019). The San Code of Research Ethics. In D. Schroeder, K. Chatfield, M. Singh, R. Chennells & P. Herissone-Kelly. *Equitable Research Partnerships: A Global Code of Conduct to Counter Ethics Dumping* (pp. 73–87). Springer.

[32] *S v. Makwanyane & Another* (CCT3/94) [1995] ZACC 3.

[33] Wright, G., et al. (2013). Ethical and Legal Implications of Whole Genome and Whole Exome Sequencing in African Populations. *British Medical Council Journal of Medical Ethics, 14*(1), 21–40.

[34] Neethling J. et al. (2005). *Neethling's Law of Personality*. LexisNexis Butterworths.

A judicial example of protecting the constitutional right to privacy and personal information is *S v. Orrie*, 2004, in which blood samples for DNA testing were taken as part of a criminal investigation without first obtaining consent for such testing.[35] Particular attention should be paid to the consent requirements for minors or persons under the age of eighteen in clinical settings, as provided for in section 129 of the South African Children's Act, 2005.

Article 71 of the SA National Health Act states that research or experimentation on a living person may only be carried out in accordance with established procedures and with the written consent of the person. The person must be informed of the purpose, the objective of the research or experiment, and any potential positive or negative effects on health.[36]

This raises the issue of the need to include a separate question on the informed consent form indicating whether the individual wishes to be informed if genetic data or genomic information relating to his or her lineage or tribe is accidentally discovered.[37] The CIOMS guidelines 2016 on the ethical criteria at the point of obtaining or accidental discovery of research results: there must be analytical validity, clinical relevance, and efficacy in order to qualify for returned results.[38]

The Promotion of Access to Information Act, 2000 gives effect to the constitutional right of access to any information held by the state or any person. Another Act, the SA Protection of Personal Information Act, 2013 requires that an individual must be given specific and explicit information about the use of his or her personal data at all times and the informed consent form must be as close as possible to the requirements of the Act. The Act emphasizes the confidentiality of medical and biometric information (including DNA information), designating these two categories as specific personal data, access to and processing of which is limited to the healthcare sector and must be in the interests of patients and clinical trial participants.

The POPI Act imposes a general prohibition on the processing of special personal information but allows for a number of exceptions, for example, where the personal data subject has consented to its processing or where the use of such information is necessary for research, statistical, or historical purposes.

It is quite rare for South African courts to hear cases involving informed consent for clinical trials. For example, *Venter v. Roche Products* (2014) was a landmark decision which dealt with a claim for non-medical harm resulting from a patient's participation

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[35] Academy of Science of South Africa & Department of Science and Technology. (2018). *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (pp. 61–62). http://dx.doi.org/10.17159/assaf.2018/0033

[36] *Id*. pp. 46–47.

[37] De Vries, J., et al. (2012). Ethical, Legal and Social Issues in the Context of the Planning Stages of the Southern African Human Genome Programme. *Medicine & Law, 31*, 119–120.

[38] Academy of Science of South Africa & Department of Science and Technology, 2018, p. 62.

in a clinical trial (pain and suffering as well as loss of income, none of which was covered by the clinical insurance policy).

The Criminal Law (Forensic Procedures) Amendment Act, 2013 contains a requirement for informed consent for biological samples, as well as provisions on access to information obtained from such samples. Article 12 of the Regulations describes the process for "removal of forensic DNA profiles from the NFDD on application": such removal must be carried out within thirty days of receipt of the relevant notifications. DNA samples for forensic purposes must be processed at an accredited laboratory that meets the appropriate ISO standard as prescribed by the South African Police Service Act, 1995, and the Forensic DNA Regulations, 2015. Clause 10(1) of the Forensic DNA Regulations provides that buccal and DNA samples must be destroyed no later than thirty days after receipt of the forensic DNA profile or processing of the DNA sample by the Forensic Science Laboratory.

According to the Accreditation for Conformity Assessment, Calibration, and Good Laboratory Practice Act, 2006, genetic testing and genomic laboratories must be accredited by the South African National Accreditation System. Meanwhile, accreditation of laboratories in South Africa is still not a legally mandatory requirement, with the exception of forensic laboratories performing genetic tests. For forensic scientists using DNA testing, the Memorandum of Understanding between the South African Council for Natural Scientific Professions and the Health Professions Council of South Africa is important.

According to Article 4(2) of the National Health Act (NHA) regulations (regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, fetal tissue, zygotes, and gametes, 2012), import and export of placental tissue, embryonic or fetal tissue, and stem cells are prohibited without written permission by the Director-General of Health. Article 4(10) of the NHA's regulations provides that biological material may only be exported to Southern African Development Community countries. However, the NHA's regulations do not cover the import of adult biological material, which is often confusing and open to abuse in practice.

In the South African context, where particular views on biological material and human data in terms of tribal identity philosophy prevail, the role of communities in genome management and their involvement in the genetic protection of their community is important. Here, a regulatory framework called the "DNA on Loan" model, pioneered by Aboriginal and geneticist researchers in Canada could prove to be quite applicable. The essence of this model is that more than anything else, the sacredness and profound religious significance of biological material to Aboriginal peoples in Canada is recognized. This principle is also enshrined in the process for releasing bio-samples in trust or on loan to geneticist researchers for specific projects. In the event that they wish to conduct further research or make the samples available to other experts, an application must be made to the Aboriginal communities who hold the authority to decide whether or not to allow such further use and also whether reuse of the samples is appropriate.[39]

The current agenda is to introduce and adapt training programs in South Africa in order to provide quality training for genetic counselors that do not currently possess adequate experience in interpreting whole genome sequencing and stranding results. Still, local clinicians and practitioners are not sufficiently trained to provide feedback to test participants and patients,[40] as medical curricula in South Africa do not take into account the rapidly evolving field of genomics and genetics. An independent and professional body, such as the Human Genetics Advisory Board, should be established to assess the genetic tests offered to patients in public and private health facilities in terms of their scientific and analytical validity and clinical utility, as well as to investigate complaints of misuse of DNA tests. Additionally, these assessments should be tailored and appropriate to the specific population and communities in South Africa (for example, in line with the values of the Ubuntu philosophy).

Conclusion

Two expert panels have been set up internationally in response to the announcement of the controversial experiment carried out by Chinese geneticist He Jiankui. The UN WHO in this regard has established a multidisciplinary expert advisory committee to systematically examine a range of issues (including scientific, ethical, social, and legal problems) related to genome editing and to subsequently develop a global framework for the regulation of legislation in this area. In addition, at the initiative of the US Academy of Sciences, the US National Academy of Medicine, and the Royal Society of London, an International Commission on the Clinical Use of Human Germline Genome Editing has been convened.

The majority of BRICS countries should also seek to establish special ethical committees in the field of genomic research and manipulation of human genetic resources, which will assess genetic scientists' and clinicians' compliance with ethical and humanistic principles in the implementation of innovative developments and genetic technologies.

Against the backdrop of rapid scientific and technological progress and a strong push for experimental medicine in the BRICS countries, a legal and ethical framework aimed at regulating genomic research and protecting genetic integrity is gradually taking shape.[41] Although in the majority of these countries, human genome research

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[39] Arbour, L., & Cook, D. (2006). DNA on Loan: Issues to Consider when Carrying Out Genetic Research with Aboriginal Families and Communities. *Community Genetics, 9*(3), 153–160.

[40] Academy of Science of South Africa & Department of Science and Technology, 2018, pp. 83–84.

[41] Travieso, J., et al. (2021). Bioethical Aspects of Human Rights in Modern Latin America. *Kutafin Law Review, 8*(1), 85–98.

is strictly controlled by state authorities, there are still many gaps in legislation and clinical practice in terms of ensuring the safety of genomic research and national biopolitics in general, which should be addressed.

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