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Ethical and Legal Landscape of Blockchain in Genetic Research

Elena N. Trikoz[1,3]✉**, Natalya O. Sidorova**[2]**, Elena E. Gulyaeva**[3]

[1] MGIMO University of the Russian Ministry of Foreign Affairs, Moscow, Russian Federation
[2] Interpol National Central Bureau, Moscow, Russian Federation
[3] Diplomatic Academy of the Russian Ministry of Foreign Affairs, Moscow, Russian Federation

Abstract

This article considers the application of blockchain technology in genetic research. The authors also pay attention to the harmonization of interests while addressing ethical and legal issues. Rapid progress in medicine and biotechnology has attracted considerable public interest to genetic information, which thus increased the amount of research in the field of genetics. Consequently, the scientific community faces new challenges pertaining to safe storage and confidentiality of vast genetic datasets. Given the unique properties of blockchain technology, it contributes to the safety, integrity and confidentiality of genetic information. The decentralized and immutable structure of blockchain simplifies safekeeping and administration of confidential genetic data. The article also explores theoretical compatibility between the structure of DNA and blockchain, hypothesizing the potential for developing artificial life forms based on blockchain technology.

The main objective of the research is to define the role of blockchain in genetics and its potential influence on the development of science and resolution of crucial legal issues. The authors conclude that blockchain technology is nowadays a reliable repository of genetic data. Moreover, this technology can form the foundation for the creation of artificial life in the short term. Although artificially created organisms may have an advantage over living organisms, they cannot exist without human control and will generate new ethical and legal issues that will require careful resolution.

Keywords: genetic research, blockchain, artificial life, data privacy

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✉Email: gulya-eva@yandex.ru

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Этический и правовой ландшафт блокчейна в генетических исследованиях

Елена Н. Трикоз[1,3]✉, Наталья О. Сидорова[2], Елена Е. Гуляева[3]
[1] Университет МГИМО МИД России, Москва, Российская Федерация
[2] Национальное центральное бюро Интерпола, Москва, Российская Федерация
[3] Дипломатическая академия МИД России, Москва, Российская Федерация

Аннотация

Статья посвящена использованию технологии блокчейн в генетике и вопросам согласования интересов при решении этических и правовых проблем в этой области. Бурное развитие медицины и биотехнологий вызвало повышенный интерес общественности к генетическим данным, увеличив количество научных исследований в области генетики. Это ставит перед учеными новые задачи, связанные с обеспечением надежной защиты и конфиденциальности больших объемов генетической информации. Уникальные характеристики блокчейна способствуют повышению уровня безопасности, надежности и конфиденциальности генетической информации. Благодаря децентрализации и неизменности своей структуры технология блокчейн облегчает процессы хранения и управления конфиденциальными генетическими данными. Кроме того, авторы рассматривают возможность объединения особенностей ДНК и блокчейна, выдвигая гипотезу о перспективах создания новых форм искусственной жизни на основе технологии блокчейн.

Целью исследования является выяснение значения блокчейна в генетике и возможного влияния этой технологии на научное развитие и регулирование ключевых правовых аспектов. Авторы утверждают, что сегодня блокчейн является надежным средством хранения генетической информации. Кроме того, существует вероятность, что эта технология станет основой для формирования искусственных живых существ в недалеком будущем. Несмотря на преимущества, которые имеют такие искусственно созданные организмы перед естественными формами жизни, они останутся зависимыми от человеческого руководства и повлекут за собой необходимость решения новых правовых и этических дилемм.

✉Email: gulya-eva@yandex.ru

Ключевые слова: генетические исследования, блокчейн, искусственная жизнь, конфиденциальность данных

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Introduction

The rapidly developing field of genetic engineering holds an important position within the realm of natural sciences. Due to their general significance, discussions around associated issues are increasingly prevalent not only in the scientific community also within society at large.

One approach for addressing some of these issues involves the use of blockchain technology, which initially emerged from the field cryptography and especially cryptocurrency. However, the legal and ethical implications of integrating blockchain technology into genetic research are multifaceted. At first glance, blockchain appears to be a suitable means for providing a secure repository for genetic information, addressing concerns related to the confidentiality and integrity of genetic data, and preventing unauthorized access by third parties. Nevertheless, the implications of using blockchain technology to create artificial life remain ambiguous and unpredictable. While such advances could potentially address issues like overpopulation and an aging population, the widespread introduction of artificial organisms into society raises significant ethical, moral, and religious concerns that yet to be fully addressed in public discourse (Gulyaeva et al., 2024).

As a result of continuous technological progress, individuals now possess the capability to conduct scientific experiments and treat numerous ailments within the comfort of their homes. In her work on genetic engineering experiments, M. Kvachadze (1999) poses a critical question: “To what extent can progress in genetics and genetic engineering in medicine be used to interfere with the essence of the human individual? How permissible is it for law, medicine, and biology to intervene in the human essence without affecting dignity or violating fundamental rights?”

The 1968 Scientific Conference on Human Rights in Tehran highlighted that, “while recent scientific discoveries and technological advances have opened vast prospects for economic, social and cultural progress, such developments may nevertheless endanger the rights and freedoms of individuals and will require continuing attention”.[1] Thus, since information about the human genome constitutes personal data, a critical intersec-

[1] United Nations. (1968). *Final Act of the International Conference on Human Rights, Teheran, 22 April To 13 May 1968*. Available at: https://docs.un.org/en/A/CONF.32/41

tion between genetics and jurisprudence appears in terms of the necessity to ensure its confidentiality as a basic aspect of individual human rights and freedoms. According to the European Court of Human Rights, the dignity of the human person must be safeguarded against potential misuse of scientific progress.[2] Due to the rapid development of genetics, the human rights framework has been expanded to include the right to protect the genetic data of individuals.

Given these considerations, establishing modern mechanisms for regulating genetic research and ensuring the protection of human genetic data becomes a moral and legal imperative. However, in addition to enhancements to legislative, additional methods not directly tied to the legal sphere can be relevant in the regulation of genetic research. One promising method is the use of blockchain technology.

The emergence of blockchain technology as a digital tool for the regulation of cryptocurrencies around a decade ago was heralded as a highly advanced mechanism for digital and financial development. While doubts about its relevance were initially raised, including among economic experts, it has become clear that the utility blockchain of extends far beyond its use in cryptocurrencies. Blockchain technology is already used in various sectors to enhance the efficiency and effectiveness of wide range of activities, such as notarial services, cadastral and title registries, tax and benefit systems, infringement and fine management, user identification, civil registration, public services, healthcare, education, art transfers, supply chains, voting systems, loyalty programs, and lotteries (Nagrodskaya, 2023). In the present article, we explore how blockchain technology has specifically contributed to advancements in genetic engineering.

Blockchain Solutions for Legal Challenges in Genetic Research

Blockchain, also known as distributed ledger technology, is a decentralized and distributed database whose structure can be represented as a chain of blocks (Kubyshkin, Kosilkin, 2021). Instead of connecting to a common server, such blocks are verified through a network of participants. This structure ensures the authenticity of transactions without the need for oversight by financial regulators. Due to the chronological record and public confirmation by all network participants, falsification of data becomes logically impossible.

Genetics has now reached a point where legal issues related to genetic research and the application of its results have become incentives. Key concerns include data security, governance and integrity. The unique properties of cooling technology, including decentralization, anonymity, autonomy, cryptographic security and the addition of time methods to each process, address these issues. (Nagrodskaya, 2023).

In practice, genetic data exhibit criticism, characteristics and normative requirements, namely historicity and inviolability (Benchoufi, Ravaud, 2017). Historicality means preserving data in chronological order, while integrity means protection from third-party interference. Blockchain technology effectively solves these problems. First, data integrity is ensured

[2] Council of Europe/European Court of Human Rights. (2016). *Bioethics and the case-law of the Court: Research report*. Available at: https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Bioethics_and_caselaw_Court_EN.pdf

through cryptographic verification of each transaction, which serves as a critical barrier to data interference (Pérez-Marco, 2016). Secondly, each transaction in the blockchain has a timestamp, which makes it easier to track and store data without disturbing its chronological order.

A distinctive feature of the blockchain is the maintenance of a decentralized and tamper-proof transaction register. Each "block" in the blockchain contains a timestamp and transaction data associated with the previous block, thus forming a continuous and immutable chain. Each "block" in the blockchain contains a timestamp and transaction data linked to the previous block, thus forming a continuous and immutable chain. In the context of genetic research, this system ensures that medical data, once entered, cannot be altered or deleted retroactively (Nehme et al., 2022). This is crucial for maintaining the integrity of long-term research, where data consistency and reliability are essential for deriving valid conclusions.

In recent years, blockchain technology has made significant inroads into the field of genetics, as evidenced by various practical implementations. For instance, Estonia pioneered the national-scale implementation of blockchain technology. Since 2005, Estonia's e-Health Foundation (EeHF) has used a blockchain approach to manage patient records (Habicht et al., 2018). In 2016, EeHF collaborated with Guardtime, a company specializing in data security, to integrate Keyless Signature Infrastructure (KSI) blockchain technology. This technology enables large-scale data authentication without relying on a centralized trusted authority, ensuring the high security, safety, and integrity of medical data (High, 2018). Today, the project encompasses over one million patient records (Alison, 2016).

Similarly, the Government of Mongolia, in partnership with FarmaTrust, launched a blockchain-based drug tracking system to combat the creation and distribution of counterfeit medicines (Ravelo, 2019; Menezes, 2022). This technology allows for the monitoring of the legitimacy of drug manufacturing conditions and delivery processes, along with the identification of points where substitutions occur, thereby halting the distribution of counterfeit medicines.

In Russia, the Novgorod Region became the pilot site for a blockchain-based drug monitoring program implemented by VNESHECONOMBANK.[3] This system helps combat counterfeiting and the leakage of expensive medicines purchased with budget funds, while also ensuring that patients in need receive their medications in full.

The Russian startup Doc.ai integrates blockchain technology with artificial intelligence. Engaging with patients using natural language, the interactive system is used to analyze genomic, pharmacogenomic, exposomic, and anatomical data. As well as collecting and evaluating information from medical sensors, the system provides an effective summary of a patient's hematological data. Doc.ai employs Neuron tokens, which provide access to the network and a means of rewarding both individual users and research organizations. These tokens also facilitate competitions on the Neuron platform, incentivizing specialists to pro-

[3] Vnesheconombank and Novgorod Region Government Launch Russia's First Blockchain-Based Project to Monitor Subsidised Medications. (2018, April 16). *Veb.ru*. Available at: https://veb.ru/en/press-center/35594/

cess and analyze medical or genetic data (Litvin et al., 2019).

Gene Blockchain, another Russian enterprise focusing on the human genome, supplies technologies and software for sequencing and analyzing genetic sequences. The processed genetic data can be used to diagnose pathologies, select appropriate medications, and determine treatment methods. By utilizing blockchain technology, Gene Blockchain makes genetic research more routine and cost-effective.[4]

ARNA Genomics, founded by Chief Scientific Officer Anatoly Melnikov, a Russian biologist and geneticist, specializes in the early detection of cancer.[5] The company has developed a blockchain-based biotechnology platform called Arna Panacea, which aims to unite stakeholders in the medical research market (Litvin et al., 2019). This platform helps expedite the introduction of new biotechnological tools to the market and creates a secure repository for clinical data on oncological diseases. It facilitates open interaction among scientists, doctors, patients, pharmaceutical companies, and insurance companies.

Beyond these achievements, blockchain technology has significant potential for broader applications in medicine. Genomic data introduce a substantial burden as data privacy and ownership issues (Ozercan et al., 2018). A significant contemporary challenge is transitioning from a reactive model of treating established pathologies to a preventive medicine approach. This novel approach relies on the analysis of large datasets to maintain and improve health by predicting potential future conditions. If leveraged correctly, personal genomics could become a primary data source for preventive medicine (Kulemin et al., 2017).

In 2014 the Genecoin project, which investigates genetic research applications of blockchain, launched a service for individuals to preserve their DNA.[6] The goal of Genecoin is to create a decentralized autonomous organization that stores genetic material indefinitely. Genecoin transforms samples of customer DNA into a special form allowing it to be stored on one of the most powerful distributed supercomputer systems represented by the Bitcoin network (Herting, 2014). Such approaches involving the idea of storing the human genome in a blockchain pave the way for blockchain services to operate independently of local and national authorities, allowing individuals to sequence their own genetic code and access it securely with a private key.

Blockchain technology, with its inherent properties of security, decentralization, and immutability, provides a universal model for recording, storing, and accessing genetic data. It offers a robust solution for advancing large-scale genetic code calculations, not only for human populations, but also for animals, plants, viruses, and microorganisms. However, critical questions about individual ownership of genetic information are raised by the potential for sequencing the genetic codes of entire populations. In addition, doubts are expressed concerning the ultimate durability of blockchain, For example, Harvard geneticist professor G. Church notes that: "The record for storage of non-living DNA is now 700,000 years (as DNA bits, not electronic bits). So ironically, the best way to preserve your electronic bitcoins/blockchains might be to convert them into DNA"

[4] *Zenome*. Avaliable at: https://zenome.io/#top
[5] *ARNA Genomics US Inc*. Available at: https://arna.bio/
[6] *Genecoin*. Available at: http://genecoin.me/

(Herting, 2014). Taking the need to replace localized repositories with larger, more comprehensive systems to permit the calculation and storage of genetic codes on a global scale, into account, distributed blockchain technology is an obvious solution for facilitating the required scalability and efficiency.

Legal issues associated with genetics are addressed in Russia through the development of a draft code of ethics, which sets out to provide a legal framework for genetic research (Kalinichenko, Ponomareva, 2019, p. 69–70). This code will address fundamental questions, including the ethical implications of human genome editing (Nedyuk, 2019). As part of this process, regulatory aspects of using cloud and blockchain technologies to store and process genetic data are additionally being explored. The draft code will guide the development of comprehensive legislation addressing all aspects of human genetic material manipulation.

Blockchain technology has also been utilized to authenticate clinical trial data, thereby enhancing the validity and reproducibility of research outcomes. Another significant application consists in the management of consent to participate in clinical trials, where blockchain may have a role in ensuring that patient consent is recorded immutably and transparently.

Globally, numerous teams of scientists and companies are dedicated to enhancing various aspects of blockchain technology as it applies to genetic medicine. As evidenced by the wide variety and popularity of blockchain projects in numerous countries, this technology offers fast and secure access to essential genetic data. However, blockchain technology in the field of genetic research presents both advantages and disadvantages.

One primary benefit of blockchain technology consists in its reliability and accessibility. Along with the systems and platforms based on them, blockchain technologies are characterized by their reliability and resistance to data loss, preventing malicious use, theft, and unsafe storage. Thus, genetic information stored on a blockchain cannot be corrupted, altered, or restored. Cryptographic keys protect genetic data and other health information while concealing the user's true identity and ensuring the confidentiality of the patient's condition. The accessibility of genetic health records stored in blockchain systems is ensured by the replication of blockchain logs across multiple nodes. Smart contract systems and cryptographic protocols in blockchain enable patients to personally control their genetic data, preventing unauthorized access and misuse (Litvin et al., 2019). Another positive aspect of Blockchain technology consists in its transparency: its inherently open nature allows its use to create a special privacy situation for its users in healthcare and genomics.

However, perhaps an even more important feature consists in the verifiability of genetic data within the blockchain system, thus ensuring data integrity and authenticity. Since all medical data in the blockchain is encoded, time-stamped, and added in chronological order, the integrity and validity of records can be verified without directly accessing the public text. This feature is particularly useful in genomic medicine and genetic research where record auditing is required to control the supply chain of pharmaceutical and biomedical drugs or to analyze data for insurance claims (Agbo et al., 2019).

A further significant advantage of blockchain in genetics is its ability to ensure close monitoring and security of personal data, as well as compliance with uniform requirements by participants in clinical trials. Blockchain-based official registries help track the quality of pharmaceutical and biomedical product components, along with their distribution, the authenticity of prescriptions, and the effectiveness of treatments (Benchoufi, Ravaud, 2017).

Limitations and challenges affecting the use of blockchain technologies in genetics issue including defining the grounds for access to genetic information, determining its volume, and identifying responsible parties. Due to its distributed nature, it can be difficult or impossible to pinpoint the responsible individual in cases of conflict or error within the blockchain system (Johnson et al., 2019). Maintaining the privacy of genetic information stored as transactions in a shared database while not revealing private personal details about the user's genome and DNA can represent particular challenges (Mathur et al., 2024). Additionally, the increasing volume of transactions involving genetic data requires more computing power and energy, raising concerns about storage space and the need to minimize data storage on the blockchain (Balis et al., 2019).

Blockchain Technology as a Platform for Creating Artificial Life

At a global intergovernmental summit last year, Jensen Huang, the CEO of the American company NVIDIA, offered an intriguing perspective on the future of learning and science. When queried about the essential areas of study amidst technological advancements, Huang remarked that the era of programming education is drawing to a close, and the future belongs to "the life sciences" (Collins, 2024). Observing that the prominence of programming skills is diminishing with the advent of technology and artificial intelligence, which are making programming more accessible, Huang contended that the era of programmers is giving way to the era of biology, citing it as one of the most intricate and least understood scientific disciplines, yet profoundly impactful on global dynamics.

Abramov et al. (2021) posited that any living organism could be described as a distributed computing system based on blockchain This perspective opens the door to the potential creation of artificial life using blockchain technology. Researchers at the US Paleontological Institute argue that blockchain technology is an ideal platform for creating living organisms (Takhokhov, 2021). This assertion is based on the structural and functional similarities between blockchain and DNA. By endowing blockchain with the key properties of living organisms, it could potentially function as a biological entity, offering advantages over naturally occurring organisms. The suggestion that blockchain technology can exhibit characteristics akin to living organisms, including growth, responsiveness to the environment, development, and self-replication implies a deep parallel with the duplication of DNA within biological cells.

Through comparative analysis between blockchain and DNA, researchers have delineated four fundamental components:

1) Blockchain demonstrates continuous growth in information volume, whereas DNA remains relatively unchanged throughout an organism's lifespan.

2) Blockchain boasts enhanced security due to a larger number of verifying nodes and cryptographic encryption algorithms.

3) DNA undergoes mutations driving Darwinian evolution, whereas blockchain maintains immutability and preserves all recorded data.

4) DNA contains numerous inactive regions, while blockchain comprises a higher density of meaningful data and instructions (Sergeev et al., 2019).

These observations hold significant implications for the advancement of biology, genetics, and medicine. However, the creation of living organisms must also be addressed from a legal standpoint. Drawing upon the principles outlined in preceding sections, it becomes apparent that a critical intersection between genetics and jurisprudence lies in the necessity to establish appropriate legal frameworks for genetic research. Specifically, this involves ensuring the confidentiality and legal safeguarding of genetic material. The aforementioned components underscore that blockchain technology enables the storage of vast amounts of information with robust security measures, while also facilitating the chronological accumulation and accessibility of data. Consequently, this engenders a "perpetual historical record" of genetic data over time.

Many researchers assert that the aforementioned developments offer humanity prospects for resurrection and widespread cloning. The current generation represents the first in history to leave genuinely reliable evidence of their lives. Future historians will be astounded by the extensive data available for studying our era. It is even conceivable that historians specializing in the 21st century and beyond may become obsolete, since the detailed documentation of events leaves little room for disagreement (Chicca, 2018).

The actions of certain researchers who are establishing startups in genetics with an eye towards the future are worth of comment in this connection. For instance, philosophers David Koepsell and Vanessa Gonzalez have founded "EncrypGen", a startup offering next-generation software for genomic data as a means of addressing gene patenting issues. The founders believe genetics holds significant promise in healthcare, with future treatments likely to be heavily reliant on patient genetic information. In this context, blockchain will facilitate tasks such as data sharing and protection through encryption, as well as tracking the utilization of genetic data. In th is connection, while blockchains are recognized for their transparency, they also paradoxically serve as a means of enhancing privacy and security while transmitting data across networks (Kubyshkin et al., 2019).

With the continuing rapid advancement of genetic and biological sciences, several key challenges emerge. Firstly, there is a need to digitize vast amounts of genetic data and consolidate them into a unified storage-cloud. Secondly, the subject of data preservation for historical, resurrection, and cloning purposes raises legal and ethical concerns.

Recording genetic data for historical preservation necessitates the consent of each individual, since genetic data are legally defined as personal information. To secure high levels of consent, assurance must be provided that individuals' genetic data are safeguarded from dissemination and interference by third parties.

Moreover, questions arise regarding the posthumous utilization of genetic data and indeed whether such data can be utilized at all. Currently, neither international nor Russian legislation regulates this aspect. Thus, it is imperative to establish not only legal norms, but also to develop a universally accepted document authorizing, prohibiting, or partially authorizing the use of a person's genetic material for scientific purposes and the creation of new living organisms. The foundation for future legislation governing genetic research may be drawn from instruments such as the Universal Declaration on the Human Genome and Human Rights of 1997,[7] as well as the International Declaration on Human Genetic Data of 2003,[8] which offer guiding principles on genetic information confidentiality, non-discrimination based on genetic data, and voluntary consent for biomaterial use. Additionally, the Federal Law on Biomedical Cellular Products of 2016,[9] provides essential frameworks reflecting international standards and principles in genetic research activities.

Ethical considerations in genetic research, particularly regarding cloning, resurrection, and posthumous data use, intersect with moral, faith-based, and religious concerns, necessitating their legal regulation. In this connection, tt may be essential to incorporate ethical and religious considerations into legal frameworks to enable individuals to refuse the deposition of their genetic data for scientific purposes.

Conclusion

A sharp reduction in the cost of sequencing the genetic code from human DNA has led to the fact that transnational blockchain genomics has increased its importance in the context of human rights and his generations, and especially the right to personal information (ownership of genetic information). The key properties possessed by blockchain technology seem destined to propel genetics into a transformative phase, thus reshaping the trajectory of human development and scientific advancement.

In the first place, blockchain technology has the potential to serve as the foundation for a mechanism facilitating the swift resolution of ethical and legal dilemmas inherent in genomic research. This mechanism would ensure the secure storage and confidentiality of genetic material, alongside its chronological recording and on-demand accessibility. Additionally, blockchain technology is steering humanity towards the creation of artificial living organisms that utilize available genetic codes. With judicious legislative regulation governing genetic research, mankind could usher in a new era and address numerous pressing challenges (Watson et al., 2017).

In addition to their use in treating diverse ailments, some researchers argue that artificially created organisms will offer advantages over naturally occurring ones. Modern neural networks can already simulate intricate human brain processes, encompassing everything from calcium spikes in individual neurons to the storage and retrieval of memories (Takhokhov, 2021). In contrast to programmed aging mechanisms affecting DNA-based lifeforms, such organisms hint at the potential to circumvent the phenomenon of aging without invoking resource scarcity concerns.

Blockchain technology represents a promising approach for addressing infertility issues and potentially replacing conventional reproductive methods. Artificial environments could facilitate the gestation of fetuses, offering novel solutions to reproductive challenges. However, two fundamental con-

[7] Unesco. (1997, November 11). *Universal Declaration on the Human Genome and Human Rights*. Available at: https://www.unesco.org/en/legal-affairs/universal-declaration-human-genome-and-human-rights?hub=387

[8] Unesco. (2003, October 16). *International Declaration on Human Genetic Data*. Available at: https://www.unesco.org/en/legal-affairs/international-declaration-human-genetic-data?hub=387

[9] *Federal Law of June 23, 2016 № 180-FZ «On Biomedical Cell Products» (with amendments and additions)*. Available at: https://base.garant.ru/71427992/#friends. *(In Russ.)*.

clusions arise from the aforementioned discussions, giving rise to pertinent questions. Firstly, artificially created organisms, although resembling living beings and demonstrating superiority in some aspects, cannot be considered fully alive, as they do not have a purely biological origin. Secondly, maintaining such organisms requires human intervention, which highlights the indispensable role of humans in their sustenance. Therefore, it would be premature to assume that the creation of blockchain-based organisms will solve the problems of aging and overpopulation, let alone displace humanity. It can be foreseen that the bright prospects of blockchain technology in genetics may face obstacles, causing conflicts between humans and artificially created organisms, as well as legal gaps in the regulation of human and artificial intelligence, protection of genetic data, recording, storage, use and potential destruction.

In this context, David Koepsell underscores the importance of maintaining a balanced approach, cautioning against overly emphasizing technology without addressing educational imperatives. Correctly applied, blockchain can empower patients and subjects, enhancing scientific data dissemination while upholding values of freedom and property. However, unscrupulous applications of this technology may overlook these concerns, for example, neglecting to actively involve customers or failing to educate them about their rights and obligations, and instead simply prioritize financial gain. It is noted that such a path may represent the easiest route for competitors in the field to obtain an advantage (Koepsell, 2019; Koepsell, Covarrubias, 2022).

Nevertheless, blockchain technology may exert a positive influence on public administration in genomic research, offering a framework for dynamically resolving ethical and regulatory controversies. By enabling real-time resolution of contentious issues in pre-trial proceedings, it thus promises to shape the future landscape of genetic research governance.

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INFORMATION ABOUT THE AUTHORS:

Elena N. Trikoz, Candidate of Science (Law), Associate Professor, Department of Theory of Law and Comparative Law, MGIMO University; Associate Professor, International Law Department, Diplomatic Academy of the Ministry of Foreign Affairs of the Russian Federation; Associate Professor of the Law Institute, RUDN University, Moscow, Russian Federation

Natalya O. Sidorova, Interpol National Central Bureau; Diplomatic Academy of the Ministry of Foreign Affairs of the Russian Federation, Moscow, Russian Federation

Elena E. Gulyaeva, Candidate of Science (Law), Associate Professor, International Law Department, Diplomatic Academy of the Ministry of Foreign Affairs of the Russian Federation, Moscow, Russian Federation

ИНФОРМАЦИЯ ОБ АВТОРАХ:

Елена Н. Трикоз, кандидат юридических наук, доцент кафедры теории права и сравнительного правоведения МГИМО; доцент кафедры международного права Дипломатической академии МИД России; доцент юридического института РУДН, Москва, Российская Федерация

Наталья О. Сидорова, Национальное центральное бюро Интерпола; Дипломатическая академия МИД России, Москва, Российская Федерацияя

Елена Е. Гуляева, кандидат юридических наук, доцент кафедры международного права Дипломатической академии МИД России, Москва, Российская Федерация