GUT MICROBIOTA BIOBANKING IN A COLOPROCTOLOGICAL HOSPITAL: ETHICAL AND LEGAL CONFLICTS AND REGULATORY PERSPECTIVES

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Biobanking of patient-isolated microbial strains is a critically important tool for modern biomedical research, though it is associated with a complex of unresolved ethical and legal issues. The goal of this paper is to analyze the issues based on biobanking case studies at the National Medical Research Center of Coloproctology named after Ryzhykh AN. The focus is on the contradictions between the need for scientific progress and respect for the rights of donors, including obtaining informed consent and ensuring data confidentiality. The study material included legal documents and internal regulations describing how to work with microbial collections. During the analysis, isolated Russian legislation, lack of a clear legal status for biological samples and dependence of ethical aspects of work on local protocols and internal policy of the institution have been found out. The key conclusion is the urgent need to develop a specialized regulatory system that harmonizes the principles of bioethics with the practical tasks of biobanking, establishing clear rules for handling a patient's microbiota and consent management mechanisms.

Keywords: biobanking, microbial strains, bioethics, informed consent, legal regulation, microbiome, personal data

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БИОБАНКИРОВАНИЕ КИШЕЧНОЙ МИКРОБИОТЫ: ЭТИКО-ПРАВОВЫЕ КОЛЛИЗИИ И РЕГУЛЯТОРНЫЕ ПЕРСПЕКТИВЫ НА ПРИМЕРЕ КОЛОПРОКТОЛОГИЧЕСКОГО СТАЦИОНАРА

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Биобанкирование штаммов микроорганизмов, изолированных от пациентов, является критически важным инструментом для современных биомедицинских исследований, однако сопряжено с комплексом не до конца решенных этико-правовых проблем. Целью данной работы является анализ этих проблем на примере практики биобанкирования в ФГБУ «НМИЦ колопроктологии имени А. Н. Рыжих». Основное внимание уделяется противоречиям между необходимостью научного прогресса и соблюдением прав доноров, включая получение информированного согласия и обеспечение конфиденциальности данных. Материалом исследования послужили правовые документы и внутренние регламенты, регулирующие работу с микробными коллекциями. В результате анализа выявлена фрагментарность российского законодательства, отсутствие четкого правового статуса биологических образцов и, как следствие, зависимость этических аспектов работы от локальных протоколов и внутренней политики учреждения. Ключевым выводом является настоятельная необходимость развития специализированной нормативно-правовой базы, которая гармонизирует принципы биоэтики с практическими задачами биобанкинга, устанавливая ясные правила обращения с микробиотой пациента и механизмы управления согласием.

Ключевые слова: биобанкирование, микробные штаммы, биоэтика, информированное согласие, правовое регулирование, микробиом, персональные данные

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Biobanking of human biological samples is crucial to personalized medicine and biomedical research [1]. However, the rapid technological advancement has exposed specific and insufficiently regulated ethical and legal aspects of formation and use of patient-isolated microbial biobanks. Despite the regulatory standards for human tissues and DNA, the status of microbial strains remains legally uncertain. Their dual nature (they function as integral components of the human microbiome, yet exist as independent, culturable, and reproducible biological entities) generates a number of difficulties. The difficulties include choosing an adequate informed consent model for the potentially indefinite use of samples, rights to commercial products developed on their basis, and regulation of rights to the samples. Kaprin AD et al. [2], note general legal gaps in Russian biobanking, while foreign researchers such as Kinkorova J [3] focus on regulatory challenges in the era of personalized medicine. Foreign practice suggests that the most promising solution is to develop multi-level consent models that respect the donor's autonomy. The purpose of this study is a comprehensive analysis of ethical and legal conflicts that arise during biobanking of patient strains of microorganisms. Using the practical cases of Ryzhykh AN National Research Medical Center for Coloproctology, the authors aim to formulate the principles for the development of internal regulations and recommendations for improvement of national regulation in this area.

Biobanking of microbial strains: scientific and clinical significance

Patient-isolated collections of authentic strains of microorganisms form a critical infrastructure of modern biomedicine. They go far beyond archiving, having a direct impact on scientific progress and clinical practice. In gut microbiome research, which is the key to coloproctology, such biobanks serve as a tool for shifting beyond just metagenomic correlations to establishing causal relationships. Access to pure cultures makes it possible to experimentally verify the role of specific bacterial taxa in the pathogenesis of colorectal cancer and inflammatory bowel diseases [4]. In the therapeutic aspect, these collections are the foundation for the development of innovative approaches from the creation of personalized probiotics and bacteriophages to the standardization of fecal microbiota transplantation [5]. In addition, the systematic accumulation of strains with clinical and epidemiological metadata creates the basis for global monitoring of antimicrobial resistance (AMR), allowing tracking the evolution of resistant clones [6]. However, the specifics of working with microbial strains create a unique ethical and legal paradox. After isolation and cultivation, the microorganism loses its direct physical connection with the donor's body, acquiring the properties of an independent biological object, which may be an object of intellectual property (for example, a patentable producing strain). It seems that it removes them from the scope of full bodily autonomy principles. But the paradox is that the scientific and clinical value of the strain is inextricably linked to the confidential data of the donor (diagnosis, treatment history, outcome). Thus, an object (thing) that is legally separable from a person retains a deeply personalized informational entity [7]. This conflict, according to which an object is separable from the body, but inseparable from personal data, constitutes the main problem that requires development of special regulatory approaches.

Ethical aspects of biobanking microbial strains

The ethics of biobanking microbial strains hinges upon solution of certain interrelated problems. The key problem is obtaining informed consent in the face of uncertainty of future research. The classical model is unacceptable here. Thus, modern practice offers to choose between the pragmatic but wide consent to the general research and a more flexible multi-tiered or dynamic consent that makes it possible for the donor to occasionally select acceptable types of research. It complies to the principle of respect for autonomy to a greater extent. Meanwhile the donor should be informed of continuous storage, possible commercialization and right to withdraw consent irrespective the selected model [8].

The issue of confidentiality is closely related to the issue of consent, as complete anonymization, where samples are totally unlinked from clinical data, is often impossible, and deprives the strain of its scientific value. Thus, pseudonymization is used that strictly limits access to data that connects the sample with the personality, requiring strict protection measures due to re-identification. The issue of ownership of the biomaterial remains unresolved in the Russian legal field: the isolated strain is not considered a "part of the body", and the right of disposal is usually assigned to the biobank institution, which creates a zone of legal uncertainty for the donor. The ethics of recycling samples for purposes not originally specified requires special attention. International standards allow such use with the approval of the ethics committee and appropriate anonymization, and a step-by-step approach is proposed: the more sensitive a new study is, the stricter the requirements for depersonalization of data should be.

Legal regulation of biobanking in the Russian Federation

The legal regulation of biobanking in the Russian Federation currently represents a multi-level and actively developing system of regulatory legal acts, which, in relation to the collection, storage and use of strains of microorganisms isolated from patients, can be divided into legislative acts, subordinate regulatory documents and national standards. The foundation of technical and terminological regulation in this area consists of national standards harmonized with international approaches. The key standard is represented by GOST R ISO 20387-2021 "Biotechnology. Biobanking. General requirements", which establishes general requirements for the competence, impartiality and consistency of the functioning of biobanks, including the processes of acquisition, identification, processing, storage and transfer of biological material and related data for research. GOST R 71251-2024 "Biotechnology. Biobanking. Terms and definitions", which establishes basic concepts such as "biobank", "biological material", "biological sample", and introduces a classification of biobanks, which allows for the unification of documentation, including the informed consent form and internal regulations for working with samples was used to ensure the uniformity of the conceptual framework.

The activities directly related to microorganisms are additionally regulated by the specialized standard GOST R ISO 24088-1-2024, which establishes requirements for the collection, processing, storage and transportation of bacteria and archaea. Practical implementation of these requirements for a medical institution is based on GOST R 59781-2021, which serves as a guide for the implementation of ISO 20387 requirements. A landmark in legal regulation was adoption of Federal Law No. 428-FZ dated November 30, 2024 "On Bioresource Centers and Biological (Bioresource) Collections". However, in the context of this study, it is important to note that according to part 2 of Article 1 of this law, its provisions do not apply to collections of pathogenic microorganisms and viruses, as well as to collections of human biological materials, which creates a legal vacuum regarding strains isolated from patients and underlines the need to develop special regulations for clinical collections. The turnover of pathogenic biological agents is regulated more strictly by Decree of the Government of the Russian Federation No. 1668 dated 30.09.2021, which approved the Rules for the Creation, Replenishment, Maintenance and Use of Collections of pathogenic microorganisms and viruses, as well as the maintenance of a national catalog of strains, and additional procedural aspects are disclosed in the Methodological Recommendations "Procedure for maintaining collections of pathogenic microorganisms", which establish requirements for accounting, storage and issue of strains.

Since working with microbial strains involves potential biological risks, the biobank's activities must strictly comply with sanitary rules. The fundamental document here is SanPiN 3.3686-21 "Sanitary and epidemiological requirements for the prevention of infectious diseases", which combined the requirements for the prevention of infectious diseases, including rules for working with pathogenic biological agents, requirements for biological safety and protection, as well as organization of premises, sterilization regime, waste disinfection and personal hygiene measures

for personnel. Other problems are related to the legal regime of information about donors, since strains of microorganisms stored in biobanks are frequently linked to clinical data, which may be subject to medical secrecy and personal data regulated by Federal Law No. 152-FZ "On Personal Data". In the context of strain biobanking, the problem of sample de-identification becomes particularly acute for research purposes while maintaining the possibility of their verification for clinical needs. The analysis shows that the legal framework of biobanking in the Russian Federation is fragmented: though the technical aspects of the activity are sufficiently regulated by national standards, the legal status of clinical collections of microorganisms, as well as the relationship between the rights of donors and the interests of researchers remain unresolved at the legislative level.

DISCUSSION OF RESULTS

The analysis helps identify a key ethical and legal contradiction attributable to biobanking of microbial strains: their dual nature, acting simultaneously as a patentable biological object and information carrier, the scientific value of which critically depends on the donor's personal data. While international research primarily focuses on human tissue biobanks, this paper focuses on the legal uncertainty that arises when patenting strains and commercializing developments based on the strains. The revealed fragmentation of Russian legislation, combined with the leading role of local ethical protocols, confirms the need to shift from the lack of a single law to the hierarchical model of management.

The solution is represented by a two-tier system that includes a framework federal law setting general principles and detailed local acts of biobanks, as it provides for the necessary flexibility in the context of the dynamic development of scientific knowledge and technological capabilities. The evolution from broad consent to multilevel models in informed consent is justified, which is a logical and necessary stage preceding the full-fledged introduction of digital platforms for dynamic consent in Russian clinical settings; this gradualness is due to both socio-cultural factors and the need to adapt the existing models of interaction with the patient to the specifics of microbial collections. The interdisciplinary approach to the development of biobank's internal policies, combining legal, ethical and scientific expertise, makes it possible to balance potential risks and integrate Russian experience in working with microbial collections into the global discussion devoted to biobanking standards, offering practical solutions that take into account both national regulatory specifics and universal ones.

CONCLUSIONS

The conducted research shows that biobanking of microbial strains isolated from patients operates under a specific ethical and legal dualism. On the one hand, the samples are independent, reproducible biological objects potentially suitable for patenting. On the other hand, their scientific and clinical value inextricably depends on confidential personal data of the donor, which creates legal uncertainty and ethical challenges that are fundamentally different from those found when working with human tissues.

The aim of the study is a comprehensive analysis of ethical and legal conflicts that arise during biobanking of microbial strains, and it can be said that principles for their regulation have been formulated. The analysis revealed that the current Russian legislation forms only a basic and insufficient framework for regulating this activity: the key gaps include the lack of a legal status for microbial strains and clear procedures for obtaining informed consent for their future uncertain research use. The area requires a specialized regulatory framework as a matter of priority, however, before the relevant federal law is adopted, it is advisable to introduce standardized local protocols at the institutional level based on the principles of responsible sample management, multilevel informed consent and transparent data management as an initial step. The results obtained can be used to develop model regulations on microbial biobanks in clinical and scientific institutions, as well as to create educational modules on bioethics for researchers and doctors working with microbial collections. Hypotheses for further study are formulated using the analysis: first, introduction of digital platforms for dynamic consent in Russian clinical practice can significantly increase the level of involvement and trust of donors in biobanking; second, a centralized national catalog of anonymized metadata of biobanks of microbial strains will increase the effectiveness of scientific collaboration and attract international investment in appropriate research in the Russian Federation.

References

1. Gottweis H, Kaye J, Bignami F, et al. Biobanks for Europe: A Challenge for Governance. European Union, 2012.
2. Kaprin AD, Ivanov SA, Petrov VA, Duhova NN, Dvinskih NÛ, Falaleeva NA, Grivcova LÛ. Biobanki v onkologii: mirovoj opyt i rossijskaâ dejstvitel'nost'. Sovremennaâ onkologiâ. 2020; 22(2): 82–88. Russian.
3. Kinkorová J. Biobanks in the era of personalized medicine: objectives, challenges, and innovation: Overview. EPMA J. 2016; 7(1): 4. DOI: 10.1186/s13167-016-0053-7. PMID: 26904153; PMCID: PMC4762166.
4. Wirbel J, Pyl PT, Kartal E, Zych K, Kashani A, Milanese A, Fleck JS, Voigt AY, Palleja A, Ponnudurai R, Sunagawa S, Coelho LP, Schrotz-King P, Vogtmann E, Habermann N, Niméus E, Thomas AM, Manghi P, Gandini S, Serrano D, Mizutani S, Shiroma H, Shiba S, Shibata T, Yachida S, Yamada T, Waldron L, Naccarati A, Segata N, Sinha R, Ulrich CM, Brenner H, Arumugam M, Bork P, Zeller G. Meta-analysis of fecal metagenomes reveals global microbial signatures that are specific for colorectal cancer. Nat Med. 2019 Apr; 25(4): 679–689. DOI: 10.1038/s41591-019-0406-6. Epub 2019 Apr 1. PMID: 30936547; PMCID: PMC7984229.
5. Sorbara MT, Pamer EG. Microbiome-based therapeutics. Nat Rev Microbiol. 2022 Jun; 20(6): 365–380. DOI: 10.1038/s41579-021-00667-9. Epub 2022 Jan 6. PMID: 34992261.
6. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022 Feb 12; 399(10325): 629–655. DOI: 10.1016/S0140-6736(21)02724-0. Epub 2022 Jan 19. Erratum in: Lancet. 2022 Oct 1; 400(10358): 1102. DOI: 10.1016/S0140-6736(21)02653-2. PMID: 35065702; PMCID: PMC8841637.
7. Federal'nyy zakon ot 27.07.2006 № 152-FZ «O personal'nykh dannykh». Russian.
8. Firsov DYe, Miroshnikov AYe, Pozdnyakov NO. Obzor rukovodstva dlya komitetov po etike «Eticheskaya ekspertiza biomeditsinskikh issledovaniy: prakticheskiye rekomendatsii» / pod obshchey redaktsiyey A. L. Khokhlova. 3-e izd., isprav. i dop. Meditsinskaya etika. 2022; 1: 10–13. DOI: 10.24075/medet.2022.038. Russian.

Литература

1. Gottweis H, Kaye J, Bignami F, et al. Biobanks for Europe: A Challenge for Governance. European Union, 2012.
2. Каприн А. Д., Иванов С. А., Петров В. А., Духова Н. Н., Двинских Н. Ю., Фалалеева Н. А., Гривцова Л. Ю. Биобанки в онкологии: мировой опыт и российская действительность. Современная онкология. 2020; 22(2): 82–88.
3. Kinkorová J. Biobanks in the era of personalized medicine: objectives, challenges, and innovation: Overview. EPMA J. 2016; 7(1): 4. DOI: 10.1186/s13167-016-0053-7. PMID: 26904153; PMCID: PMC4762166.
4. Wirbel J, Pyl PT, Kartal E, Zych K, Kashani A, Milanese A, Fleck JS, Voigt AY, Palleja A, Ponnudurai R, Sunagawa S, Coelho LP, Schrotz-King P, Vogtmann E, Habermann N, Niméus E, Thomas AM, Manghi P, Gandini S, Serrano D, Mizutani S, Shiroma H, Shiba S, Shibata T, Yachida S, Yamada T, Waldron L, Naccarati A, Segata N, Sinha R, Ulrich CM, Brenner H, Arumugam M, Bork P, Zeller G. Meta-analysis of fecal metagenomes reveals global microbial signatures that are specific for colorectal cancer. Nat Med. 2019 Apr; 25(4): 679–689. DOI: 10.1038/s41591-019-0406-6. Epub 2019 Apr 1. PMID: 30936547; PMCID: PMC7984229.
5. Sorbara MT, Pamer EG. Microbiome-based therapeutics. Nat Rev Microbiol. 2022 Jun; 20(6):365–380. DOI: 10.1038/s41579-021-00667-9. Epub 2022 Jan 6. PMID: 34992261.
6. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022 Feb 12;399(10325): 629–655. DOI: 10.1016/S0140-6736(21)02724-0. Epub 2022 Jan 19. Erratum in: Lancet. 2022 Oct 1; 400(10358): 1102. DOI: 10.1016/S0140-6736(21)02653-2. PMID: 35065702; PMCID: PMC8841637.
7. Федеральный закон от 27.07.2006 № 152-ФЗ «О персональных данных».
8. Фирсов Д. Е., Мирошников А. Е., Поздняков Н. О. Обзор руководства для комитетов по этике «Этическая экспертиза биомедицинских исследований: практические рекомендации». Под общей редакцией А. Л. Хохлова. 3-е изд., испр. и доп. Медицинская этика. 2022; 1: 10–13. DOI: 10.24075/medet.2022.038.