

## ETHICAL ISSUES OF NEUROTECHNOLOGY

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Discussion of the draft of the Recommendations on the Ethics of Neurotechnology proposed by UNESCO reveals the need to develop domestic regulations in this area, taking into account modern challenges of technological development. The purpose of the recommendations in the field of neuroethics is to ensure the human right to protect health, well-being and dignity associated with the risks of technological interference in the brain and mental processes, as well as threats associated with the social and humanitarian consequences of scientific and technological progress in the field of neuroscience and neurotechnology. The draft of domestic recommendations should establish obligations related to the ethical aspects of creation, implementation and use of neurotechnologies, which are currently not regulated by the legislation of the Russian Federation and acts of technical regulation. The objectives of the recommendations are to specify the terminological apparatus in accordance with the current regulatory legal acts, targeted separation of neurotechnologies for medical and non-medical purposes, ensuring safety for the health and well-being of vulnerable persons and social groups. In the socioeconomic aspect, development of domestic recommendations on the use of neurotechnologies shows the relevance of stimulating development of domestic production and socioeconomic growth in accordance with the national development goals of the Russian Federation until 2030.

**Keywords:** neurotechnology, neuroethics, neurolaw, technological progress, neural interfaces

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## РАЗРАБОТКА ЭТИЧЕСКИХ РЕКОМЕНДАЦИЙ В ОБЛАСТИ ВНЕДРЕНИЯ НЕЙРОТЕХНОЛОГИЙ

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Обсуждение предложенного ЮНЕСКО проекта Рекомендаций по этике нейротехнологий выявляет необходимость разработки отечественных регламентов в данной области с учетом современных вызовов технологического развития. Целью рекомендаций в сфере нейроэтики является обеспечение права человека на защиту здоровья, благополучия и достоинства, связанных с рисками технологического вмешательства в мозг и ментальные процессы, а также угроз, связанных с социально-гуманитарными следствиями научно-технического прогресса в области нейронаук и нейротехнологий. Проект отечественных рекомендаций должен установить обязательства, связанные с этическими аспектами создания, внедрения и использования нейротехнологий, которые в настоящее время не урегулированы законодательством Российской Федерации и актами технического регулирования. Задачами рекомендаций являются конкретизация терминологического аппарата в соответствии с действующими нормативными правовыми актами, целевое разделение нейротехнологий медицинского и немедицинского назначения, обеспечение безопасности для здоровья и благополучия уязвимых лиц и социальных групп. В социально-экономическом аспекте разработка отечественных рекомендаций применения нейротехнологий отражает актуальность задачи стимулирования развития отечественного производства, социально-экономического роста в соответствии с национальными целями развития Российской Федерации до 2030 г.

**Ключевые слова:** нейротехнологии, нейроэтика, нейроправо, технологический прогресс, нейроинтерфейсы

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In April 2024, UNESCO headquarters in Paris announced the work of an Ad Hoc Expert Group (AHEG) consisting of 24 international experts on development of the first draft of Recommendations on the Ethics of Neurotechnology. Between May and July 2024, global and regional consultations were held “in order to take into account the views of a wide range of key stakeholders and different points of view in order to ensure an open and inclusive process for developing the draft of Recommendations” [1]. Russian experts took part in discussion of the UNESCO project. In particular, consultations held during the All-Russian Conference on Bioethics and Global Social Transformations at Yaroslavl State Medical University on June 28, 2024 were participated by members of the

Russian Committee on Bioethics under the Commission of the Russian Federation for UNESCO [2]. Based on the results of the discussions to be held in 2024–2025, the final text of the Recommendations will be submitted for consideration at the 43rd session of the General Conference in November 2025 [1].

The active discussion of the draft of Recommendation on the Ethics of Neurotechnology reflects the Records of the General Conference 42nd session, Paris, November 7–22, 2023, on the need to create a global “ethical framework” to address human rights issues that arise or may arise in connection with the introduction of neurotechnologies into practice. Participation of Russian experts in the discussion of the draft makes it possible to draw attention of the international

community to issues that require additional clarifications, taking into account regional and national interests.

The pressing issues of the use of neurotechnologies in medical practice discussed by Russian experts and the prospects for spread of neurointerfaces in the consumer market reflect the need to develop domestic regulations in the field of neuroethics concerning both the most common topics of global prospects for neurotechnological progress and interests of domestic science.

Preparation of domestic recommendations is one of the solutions to the problems associated with modern challenges of technological development, defined by the Concept of Technological Development for the period up to 2030 as “objectively requiring a response from the state and society, a set of problems, threats and opportunities in the field of technology development and implementation, the complexity and scale of which are such that they cannot be solved, eliminated or implemented without structural changes solely due to increased resources” [3].

The purpose of domestic ethical recommendations on introduction of neurotechnologies can be determined taking into account a wide range of neurointerfaces applied in medical and social practice. The purpose of the recommendations in the field of neuroethics is to ensure the human right to protect health, well-being and dignity associated with the risks of technological interference in the brain and mental processes, as well as to prevent threats associated with the socio-humanitarian consequences of scientific and technological progress in the field of neuroscience and neurotechnology.

When discussing and developing the draft of domestic recommendations in the field of neuroethics, it is necessary to take into account the relevance of previously adopted international agreements, including provisions of the Nuremberg Code (1947), Universal Declaration of Human Rights (December 10, 1948), Helsinki Declaration of the World Medical Association on the Ethical Principles of Medical Research with Human Participation (1964–2013), Convention on the Protection of Human Rights human rights and human dignity in connection with the use of biological and medical preparations: the Convention on Human Rights and Biomedicine of the Council of Europe (April 4, 1997 Oviedo), Montreal Declaration on the Responsible Development of Artificial Intelligence (2017), Ethics Guidelines for Reliable AI of the Council of Europe’s High-Level Ad Hoc Expert Group (2018), Global Initiative for Ethics of Autonomous and Intelligent Systems (IEEE, 2016), Recommended Practices for Quality Management of Datasets for Medical Artificial Intelligence (IEEE), Model the Convention on Robotics and Artificial Intelligence (2018), Concept of Development of Regulation of relations in the field of artificial intelligence and robotic technologies until 2024 (2020), Code of Ethics of Artificial Intelligence (2021), taking into account the expert experience of the International Committee on Bioethics (ICD) and Intergovernmental Committee on Bioethics (IPCB), World Commission on Ethics of Scientific Research knowledge and Technology (COMEST), as well as a number of other international documents.

The axiological basis of the dialogue on the prospects of neurotechnology can be the established domestic bioethical discussion, summarizing the ideological value priorities of the scientific community in accordance with the legislation and taking into account historical experience of domestic healthcare, general goal-setting of scientific and technological development, criteria for progress in an actual and promising (prognostic) meaning. Reliance on bioethical thinking makes it possible to consciously apply bioethical axiology to scientific

research, practical healthcare and social practice on the basis of a successive and continuous semantic correlation of professional knowledge and its axiological periphery, “knowledge about knowledge”.

The draft of domestic neuroethical recommendations should establish obligations related to the ethical aspects of creation, implementation and use of neurotechnologies, which are currently not regulated by the legislation of the Russian Federation and acts of technical regulation. The basis of the recommendations should include general principles, which, if necessary, can be extrapolated in certain areas of neurotechnology application, taking into account the specifics of the goals of application and practical tasks to be solved, both medical and non-medical, as well as predicted risks.

One of the primary tasks of developing domestic recommendations should be specification of the terminological apparatus in accordance with current regulatory legal acts, documents of strategic planning and regulatory and technical regulation in the field of neurotechnology, including the provisions of the Strategy for Scientific and Technological Development of the Russian Federation, Strategy for the Development of the Information Society of the Russian Federation, National Development Goals of the Russian Federation for the period up to 2030 and for the future until 2036, and Roadmap for the development of “end-to-end” Neurotechnology and Artificial Intelligence digital technology [4].

Taking into account the provisions of the above acts, the following definitions can be given to the basic concepts of the recommendations:

- neurotechnologies include technologies that use or help to understand the work of the brain, thought processes, higher nervous activity, including technologies to enhance and improve brain function and mental activity;
- neuroimaging includes structural and/or functional visualization of the brain by computed tomography (CT), magnetic resonance imaging (MRI), functional magnetic resonance imaging (fMRI), positron emission tomography (PET), and magnetoencephalography (MEG);
- neuroethics is an interdisciplinary field of research, the subject of which is the impact of neurotechnologies on all areas of human activity. Invasive brain intervention is a direct effect on brain structures, including methods of invasive neurostimulation and neuromodulation through direct stimulation of the nervous system by surgical implantation methods, comprising the therapeutic use of deep brain structure stimulators (DBS), as well as invasive MRI methods;
- noninvasive intervention in the brain includes effects on brain structures without implantation of stimulants, including methods of transcranial magnetic stimulation and transcranial electrical stimulation;
- registration of biometric brain indicators or identification based on unique personal information obtained on the basis of biometric screening of brain indicators.

The recommendations should reflect, at the level of defining clear goals, demarcation of medical neurotechnologies and neurotechnologies for improving the functions of the brain and nervous system of healthy people, including their widespread consumer use in education, sports and for entertainment purposes, taking into account specifics of the computer game industry, designed for the widest audience, including vulnerable groups of persons.

The targeted separation of neurotechnologies for medical and non-medical purposes can be based on the principle of

established necessity. In medical practice, satisfaction with an established objective need is the criterion for the need to use neurotechnologies. The risks assumed in this case should be assessed in comparison with the predicted positive results. The use of neurotechnologies for non-medical purposes as a way to create benefits should be considered from the perspective of ensuring their safety for human physical and mental health.

The basis for assessing the necessity factor may be the procedural bioethical model for implementation of the content of responsibility proposed by Russian researchers [5–7].

The criterion for the expediency of introducing neurotechnologies is their use exclusively in the interests of the consumer or patient and in full accordance with the stated purpose, purpose, objectives and methods of use. In this direction, the recommendations should prevent a discrepancy between the stated goals of the technological direction of neurotechnological developments and the real needs of users. This means that, recognizing the consumer's right to free access to neurotechnologies, it is necessary to ensure it on the basis of effective cooperation of all subjects involved in implementation and application of a neurotechnological project such as researchers, developers of technology (neurointerfaces), software owners, and the recipient of services. At the same time, it is necessary to ensure compliance with the conditions of informed choice, without any discrimination, coercion or violence, based on forecasts, needs and opportunities focused on the interests of the individual and society. In this aspect, the principles of fair competition and effective cooperation among researchers, developers and businesses interested in publishing accessible, reliable and comparable information are of great importance.

Observance of these principles will be consistent with ensuring the safety of people and society in the dissemination of neurotechnological innovations not only by state control bodies, but also by local ethical committees at both the state and interstate levels.

The recommendations should reflect the challenges of the potential capabilities of neurotechnologies to control, monitor and influence brain processes. It is necessary to prevent the use of neurointerfaces to control behavior and personality traits. Neurotechnologies in medicine expand the understanding of how the brain generates certain forms of behavior, but the results should be used exclusively for the purpose of studying the work of the brain, thought processes, and higher nervous activity.

Ensuring safety for human health and well-being is especially relevant for vulnerable individuals and social groups. For people with special rights (disabilities), rehabilitation neurotechnologies and equipment (“smart” things, “connected technologies”) are the solution to the problems of socialization. At the same time, there are risks of using individual traits of patients in predicting rehabilitation prospects (“machine ageism”).

Patients with polymorbid pathologies, manifestations of combined pathologies seen as changes in the clinical picture and course of the disease are included into a separate category of risk groups. Regardless of the leading pathology, the factors of the course of the disease are the complication of diagnosis, choice of tactics, goals, objectives and means of treatment against the background of a general decrease in quality of life.

The use of neurotechnologies in relation to patients with mental pathologies should take into account the factors of their identity, development of cognitive, communicative and creative abilities, severity of motor coordination problems, behavioral and emotional disorders in order to prevent destructive interference with the mental identity and mental integrity of a person for the patient.

Development and implementation of domestic recommendations, in addition to the main tasks of establishing rules for neurotechnological development, as well as formation of a market for neuroservices, should popularize and build consumer confidence in the positive effects of using neurotechnologies, primarily for medical purposes. In order to form correct user expectations, it is necessary to ensure that user requests correspond to the real capabilities of neurotechnologies. In this context, responsibility of developers and manufacturers includes reliable, complete and user-accessible information about the goals, principles and risks of using neurotechnology, including the possibility of unpredictable, unforeseen consequences associated, in particular, with neural services, with the interaction of neurotechnologies and artificial intelligence (AI). A potential consumer should be aware of the influence of neuropractices on mental and intellectual processes related to the emotional sphere, choice and will of a person. Development of the neuromarket will inevitably be accompanied by advertising offers and consumer product presentations. When making recommendations in this segment, it will be necessary to focus on the compliance of information for the purpose of selling a product with data from randomized scientific studies confirming the principles of operation and effectiveness of the advertised devices.

A consolidated attitude to the problem of the professional medical community, developers, suppliers and recipients of services should be a guarantee of reliable management, ethical control and deontological support for the introduction of neurotechnologies into medical practice and non-medical consumption.

The widespread use of neuroethical recommendations will also reduce the risks of “biohacking” associated with a gradual reduction in price and increased accessibility of technologies for the mass consumer, which carries both immediate risks for the consumer and reputational risks for the professional community.

In the socioeconomic aspect, development of domestic recommendations for the ethical regulation of the introduction of neurotechnologies reflects the urgency of the task stimulating domestic production by establishing and ensuring transparent and stable regulatory rules of behavior and interaction of subjects of technological development, improving scientific directions and putting results into practice by optimizing the scientific and ethical paradigm that reflects real progress. Ethical regulation optimizes the conditions for socioeconomic growth in accordance with the national development goals of the Russian Federation until 2030 and national interests, including the ones used to create its own scientific, personnel and technological base of critical and end-to-end technologies that ensure production of high-tech products.

It is necessary to note the importance of the dialogue on neuroethics in solving the problems of attracting young specialists to the discussion of science development. On November 28–30, 2023, the III Congress of Young Scientists was held at the Sirius federal site, within which a session “Scientific search and ethical and legal issues of research activity” was organized in the format of a meeting of the working group on regulatory legal regulation and bioethics in the field of genetic technologies [8]. The competition of professional achievements of students, residents and postgraduates entitled Start to a Successful Future. Bioethics and Challenges of Technological Development, participated by novice scientists studying under specialist, bachelor, master, residency, postgraduate programs, held by the Yaroslavl regional branch of the All-Russian Public Organization “Russian Professional Assembly” and Federal State Budgetary Educational Institution of the Ministry of Health of the Russian Federation, is aimed

at forming interest in issues of science ethics. [9]. Educational projects are of great importance, primarily the ones aimed at young scientists, in particular the “School of Ethics of Scientific Research”, as well as comprehensive scientific research at the junction of ethical and legal foundations of a specialist’s activity in various fields of practical healthcare [10–12].

Thus, discussion, development and implementation of domestic recommendations in the field of neurotechnology into medical and social practice are a requirement of the time, an objective need to regulate both the processes of technological progress and the new field of human rights, neurorights.

The specific feature of neurotechnology application is their accelerated development with the rapid transition of projects into the field of wide non-medical application, with the formation of trends in the use of neurointerfaces in various fields of social practice, as well as the convergence of neurotechnologies, biometric and digital technologies, and artificial intelligence. It is necessary to ensure a comprehensive multi-level examination of projects before their introduction into practice and a system for monitoring the biological, socio-humanitarian and economic consequences of the use of medical and non-medical neurotechnologies.

The general provisions of the recommendations on the use of neurotechnologies should relate to all areas of current and potential interest of developers, researchers, and representatives of science in the use of neuroprocedures, including widespread consumer use in education, sports, and leisure. The general principles of ethics and human rights herein should be based on the basic values developed by the scientific community in accordance with social progress experience and recognition that the integrative category of health is determined not only by the level of scientific research and technological achievements, but also by the quality of psychosocial and socio-cultural factors. All aspects of a person’s identity should be taken into account, including biological, psychological, social, cultural and spiritual indicators. It should be borne in mind that decisions based on objective ethical issues of the development of medicine and the “life sciences” in general, as well as related technologies, can have an impact on individuals, families, groups or communities, as well as on humanity as a whole. The widest possible discussion on the ethics of neurotechnology should provide adapted mechanisms for the reasonable regulation of technological development for the benefit of the individual and society.

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