Translation

The following guidelines, issued by a Chinese Communist Party commission, offer non-binding principles for ethical conduct in brain-computer interface research. The guidelines categorize BCI technology by its level of invasiveness, and distinguish therapeutic BCI designed to help people with neurological disabilities from augmentative BCI that enhances the abilities of healthy people. The guidelines urge "moderation" in the adoption of BCI technology, particularly in the case of augmentative BCI, which the guidelines warn could exacerbate social inequality if adopted without restraint.

Title
Ethics Guidelines for Brain-Computer Interface Research
脑机接口研究伦理指引

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Ethics Guidelines for Brain-Computer Interface Research

1. Purpose

To guide the compliant conduct of brain-computer interface (BCI) research, prevent ethical risks in the research and application of BCI technology, and promote the healthy and orderly development of this field, this document proposes ethical guidelines for BCI research.

2. Terminology

2.1 Brain-Computer Interface (BCI):

BCI is a new interdisciplinary technology that creates an information channel between the brain and an external device to achieve direct information exchange between the two. It involves collecting the brain's neural activities from inside or outside the skull using recording devices, decoding these activities via machine learning models to extract information like subjective intentions, and using this information to output corresponding commands to control external devices, creating an interactive closed-loop system. BCI applications mainly include healthcare and medicine, communication, and lifestyle and entertainment, especially improving the movement, communication, and perception functions of patients with neurological paralysis diseases.

2.2 Noninvasive BCI:

Refers to BCI technologies that collect brain signals in a noninvasive manner from outside the scalp, including scalp electroencephalogram (EEG) and functional near-infrared [spectroscopy] signals.

2.3 Invasive BCI:

Refers to BCI technologies that involve neurosurgical procedures to implant electrodes or other signal recording devices into specific brain areas for precisely positioned and high-throughput neural signal collection.

2.4 Interventional BCI:

Refers to BCI technologies where electrodes or other signal recording devices are introduced into specific brain regions through interventional surgery for low-damage, high-precision, and high-throughput neural signal collection inside the brain.

2.5 Restorative BCI:

BCI technologies that help clinical patients or people with disabilities recover and substitute some lost functions, including sensory, motor, and language functions.

2.6 Augmentative BCI:

BCI technologies that enhance the sensory, cognitive, and motor abilities of users with normal bodily functions.

2.7 Electroencephalogram (EEG):

Records the electrical signal changes when the brain is active, reflecting the overall electrical activity of neural cells on the surface of the brain or scalp.

3. Basic Principles

3.1 Ensure Health, Enhance Well-Being:

BCI research should be undertaken in moderation (适度) and be harmless. The fundamental purpose of the research is to assist, enhance, and repair the sensory-motor functions of the human body or improve human-computer interaction capabilities, thereby enhancing human health and well-being.

3.2 Respect Participants, Apply in Moderation:

BCI research should respect the right to know (知情权) and personal dignity of participants, respect their autonomy in decision-making, and ensure the integrity of the human brain in terms of structure, function, and mental consciousness to the greatest extent possible. BCI research should fully consider the risks and benefits. Studies involving the neural development of children and adolescents should adopt stricter ethical evaluation, review, and risk prevention measures. The development of augmentative brain-computer interfaces should follow the principle of moderation. In the absence of proper handling of various risks, related technological applications should not be rashly undertaken, so as to minimize negative impacts on humans.

3.3 Adhere to Justice, Ensure Fairness:

Key technologies, performance indicators, and access pathways of BCI research should be open and transparent, ensuring fairness in accessing BCI technology. Strictly regulate the application of BCI technology in medical, educational, employment, and other competitive social areas to ensure fairness in social competition. Prevent bias and discrimination between the BCI target audience and non-target audience, and provide assurance for the legitimate rights and interests and fair treatment of both the target audience and non-target audience.

3.4 Control Risks, Ensure Safety:

BCI research should adhere to high scientific standards, professional norms, and ethical principles. Ensure high-quality research design, effectively control research risks, and conduct ethical reviews and data security reviews of research proposals and results. Promote risk monitoring throughout the research process, dynamically adjust risk control and management measures, and protect the physical safety, privacy, personal information, data security, and legitimate rights and interests of participants.

3.5 Information Disclosure, Assurance of the Right to Know:

BCI research should actively share information, ensuring openness and transparency, and safeguarding the right to know for all stakeholders. Relevant research should accurately and in a timely manner disclose information and report

research results to ensure the quality of research. When involving new and potentially controversial technologies, it should be fully discussed, and the opinions of stakeholders and the public should be widely heard.

3.6 Support Innovation, Strictly Regulate:

For rare diseases that seriously endanger life and for which no other effective treatment exists, clinical trials of innovative brain-computer interface products may be conducted with full informed consent, provided that there is strict compliance with national regulations concerning medical devices, clinical research, and other related stipulations.

4. General Requirements

4.1 Legal and Regulatory Compliance

BCI research must comply with relevant national laws and regulations, follow internationally recognized ethical standards, and adhere to the professional consensus and technical specifications agreed upon by the scientific community. It is prohibited to engage in illegal activities, infringe on others' legitimate rights and interests, or disrupt social stability through BCI research. Spreading false advertising information that does not match the actual effects of the BCI is not allowed.

When conducting brain-computer interface research on humans, applications must be made according to relevant regulations such as the *Ethical Review Measures for Life Science and Medical Research Involving Humans* and pass ethical review. It is necessary to fully verify the safety and efficacy based on the guiding principles and relevant standards for surgical implants and active implantable devices, including providing biocompatibility test reports, type testing reports, and large animal safety and efficacy reports.

Invasive BCI research should be conducted with sufficient evidence of safety and benefit. Medical personnel must adhere to a patient-centered approach, uphold professional ethics, and strictly comply with laws and regulations, standards, and institutional medical quality management provisions related to medical quality management. They must regulate clinical diagnosis and treatment behaviors, ensure medical quality and safety, and avoid or minimize tissue damage and infection risks during and after surgery to the greatest possible extent to ensure patient safety.

4.2 Social and Scientific Value

Those who engage in BCI research should ensure their research has social value, mainly focusing on restorative BCI technologies and emphasizing serving health needs of the public through the development of technology. Non-medical purposes such as

attention modulation, sleep regulation, memory regulation, and exoskeletons for augmentative BCI technologies should be explored and developed to a certain extent, provided there is strict regulation and clear benefit. The research design should be scientifically rational, operable, and of scientific value.

4.3 Informed Consent

BCI researchers must obtain written informed consent from participants or their guardians/legal representatives. Participants must be fully informed of the risks and benefits of surgery and related treatments before participating in the study. The informed consent form and process should be standardized and approved by the ethics review committee. If new risk information is discovered or may affect participants' willingness, informed consent must be re-obtained. Participants are allowed to withdraw at any stage unconditionally.

4.4 Privacy and Personal Information Protection

Neural data or experimental samples collected during BCI research reflect participants' mental states, physiological health, personality traits, and wealth information, constituting private data. The scope of data collected and access permissions for personnel should be approved by the ethics committee. A proper handling and management plan should be established, and data or samples should be protected throughout the process of collection, storage, use, processing, transmission, and publication in accordance with relevant laws, regulations, and technical standards on information security management. Compliance with laws and regulations such as the *Personal Information Protection Law of the People's Republic of China* and the *Data Security Law of the People's Republic of China* is required to strengthen risk monitoring, prevent data or sample leaks, and safeguard data security and participants' privacy and personal information.

4.5 Risk Control

BCI research should establish a safety risk control mechanism, including strict operating procedures, correction mechanisms for common mistakes, emergency plans, suspension procedures, and remedial emergency response guidelines to ensure participant safety. Strengthen device and equipment identity authentication, information encryption, and system protection mechanisms, and establish emergency handling mechanisms. Continuous attention to and resolution of internal system security risks are required to enhance system reliability, controllability, and security. Conduct long-term system security evaluations and validations, and ensure the long-term security of systems.

4.6 Aptitude Requirements

Individuals conducting BCI research should have the appropriate professional level and ability and undergo specialized skill and ethical training. Clinical research involving patients as research subjects must involve clinicians and comply with clinical research requirements. Research teams and relevant research institutions should possess the necessary key technologies, research prerequisites, and infrastructure. Invasive BCI research should use professionally certified equipment, and the safety of drugs and devices should comply with legal regulations and national standards such as the *Drug Administration Law of the People's Republic of China* and the *Regulations on the Supervision and Management of Medical Devices*.

4.7 Responsibility Mechanism

BCI research should enhance system transparency, explainability, reliability, and controllability, ensuring accountability at stages such as technology design, R&D, use, and deployment; obey national laws, regulations, and standards, and clearly define the responsibility mechanism among BCI product and service providers, researchers, and subjects.

5. Research Types

5.1 Non-Invasive Restorative BCI Research

Non-invasive restorative BCI research collects patients' brain signals in a non-invasive manner, decodes the signals to generate commands to control external devices, improving patients' mobility, communication, and other functions, thereby enhancing their quality of life.

BCI research should benefit the health of the human brain and body. Given the brain's extreme fragility and sensitivity, researchers should bear the burden of proof during the ethics review process, fully explaining the risks and preventive measures of the research; researchers must clearly inform subjects of potential research risks and the risk-benefit assessment, obtaining explicit consent from the subjects or their legal representatives, and respecting the subjects' right to withdraw at any time.

In research, the safety of devices in contact with the human body must meet relevant national standards or norms, continuously address and resolve internal system safety risks, and improve the system's short-term and long-term safety levels; strictly control research that intervenes in the thinking, mental, and neural activities of individuals, avoiding all direct and indirect harm and respecting human autonomy; brain signal data collection, storage, processing, transmission, and publication processes should be transparent to the subjects, strictly adhering to relevant laws, standards, and norms, ensuring data security and the privacy of the subjects; it is

essential to fully understand the impact of BCI research on the neural development of children and adolescents, taking strict ethical evaluation and preventive measures against potential physical and psychological harm and rights infringements.

5.2 Invasive Restorative BCI Research

Invasive restorative BCI research typically requires neurosurgical procedures to implant devices such as electrodes inside the brain to collect neural signals. These signals are decoded to generate commands controlling external devices or neural stimulation, improving patients' sensory, cognitive, and motor functions, thereby enhancing their quality of life.

Invasive BCI carries short-term and long-term safety risks associated with neurosurgery and implant placement. Therefore, in addition to adhering to the ethical guidelines relevant to non-invasive restorative BCI, the following requirements must be followed for invasive restorative BCI research:

In the research, it is necessary to follow national laws, regulations, standards, and norms, and adhere to medical ethics norms. It is essential to fully assess the risks and benefits and compare them with other treatment methods. Only after thoroughly considering and avoiding physical and rights harms, and based on sufficient scientific evidence, through a rigorous and careful procedure, can the necessity and rationality of employing invasive BCI technology be determined. Strict adherence to the norms of medical surgery is required. Specialists should perform the implantation of electrodes and other devices, striving to minimize tissue damage and infection risks during and after surgery. Long-term safety risks, including brain damage, inflammatory responses, skin erosion, abnormal bone growth, and risks of electromagnetic radiation, must be monitored. The attenuation or loss of brain signals during the research process, as well as device failure, must be promptly addressed to ensure patient safety. After the research, doctors should decide whether to remove the implants based on the patient's condition to maximize patient safety.

5.3 Interventional BCI Research

Interventional BCI research usually involves interventional surgery to introduce sensors into specific brain areas via blood vessels. These sensors collect neural signals from the brain, and based on signal decoding, generate commands to control external devices or neural stimulation. This improves patients' perception, cognition, and mobility, enhancing their quality of life.

Interventional BCI carries short-term and long-term safety risks associated with the surgery and placement of devices inside blood vessels. Therefore, beyond adhering

to the ethical guidelines related to non-invasive and invasive BCI, interventional BCI research must follow these requirements:

In research, it is necessary to strictly follow medical standards for interventional surgery, comply with national laws, regulations, standards, and norms, and have specialized personnel carry out the interventional surgery and the introduction of interventional sensors into blood vessels to minimize the short-term risks of vascular injury during the introduction process. It is also important to monitor the long-term risk of infection of the introduced devices, closely observe adverse reactions such as intravascular thrombosis, monitor the patient's coagulation status to reduce the risk of coagulation dysfunction, and monitor long-term risks where the interventional sensor may lose signal or become disabled due to tissue encapsulation (组织包裹) and inflammatory responses, ensuring patient safety. After the study concludes, doctors should decide whether to remove the introduced devices based on the patient's condition to ensure the patient's safety to the greatest extent.

5.4 Augmentative BCI Research

Augmentative brain-computer interfaces refer to non-invasive BCIs that enhance the sensory, cognitive, and motor abilities of individuals with normal body functions. Since this technology is still in its early stages of development, the scope of its application, the appropriate degree of enhancement, and its long-term impacts on humans are not yet clear, presenting unknown risks.

In addition to adhering to the ethical guidelines related to non-invasive restorative BCIs, augmentative BCI research should follow these requirements: thoroughly assess risks and benefits, use the technology in moderation, minimize negative impacts on humans; strictly control research that could lead to addiction or affect normal human thought and behavior; strictly regulate the application of this technology in competitive social fields to ensure fair competition in society; emphasize human autonomy, avoid replacing or weakening human decision-making capabilities with augmentative BCI technology before it is proven to surpass human levels and gains societal consensus, and avoid research that significantly interferes with or blurs human autonomy and self-awareness.

5.5 Animal BCI Research

Animal experiments have laid a solid foundation for advancing human BCI research and applications. In the process of animal BCI research, which involves surgery, experiments, and care and feeding, improper handling can harm the welfare of the animals and even endanger their health and safety. Animal BCI research should comply with China's *Regulations on the Management of Laboratory Animals* and *Guiding Opinions on Treating Laboratory Animals Well*, among other relevant

management regulations, following the principles of "replacement, reduction, and optimization."

6. Science Popularization Propaganda

Researchers involved in BCI studies should actively participate in and conduct S&T popularization activities for the public, helping the public to correctly understand the purpose and significance of BCI research.

When publishing BCI research findings, researchers should objectively and accurately evaluate the results, avoid one-sided exaggeration of the study's findings, promptly correct misleading statements, guide the public to view BCI research findings scientifically, and foster a favorable atmosphere for the development of BCI technology.

This guideline was developed by the Artificial Intelligence Ethics Subcommittee of the National Science and Technology Ethics Commission, with regular assessments and timely revisions.

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