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# *The Legal Risk and Regulation Path of Brain-Computer Interface Technology*

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***Abstract.*** Brain-computer interface technology is moving from laboratories to clinical and industrial applications at an unprecedented speed, and the legal risks derived therefrom have exceeded the responsive capacity of traditional civil laws. This paper demonstrates its argument following the approach of "risk typology – regulatory systematization". Brain-computer interface technology has three key characteristics in legal evaluation, namely direct intervention, bidirectional interaction, and identifiability and inferability of neural data. It impacts the mind-body dualistic structure and the subjective status of human beings, thereby triggering three progressive types of risks: personal rights and interests, neural information legal interests, and autonomy of will and liability bearing. The current norms in China have obvious deficiencies in three dimensions: subjectivity, remedy and responsiveness. In this regard, a regulatory path should be constructed following the three-stage logic of "right justification – norm improvement – regulatory innovation", so as to seek a dynamic balance between humanistic order and technological progress.

***Keywords:*** Brain-computer interface, neural information, personality rights and interests, emerging rights, regulatory sandbox

## 1. Introduction

In recent years, Brain-Computer Interface (BCI) is no longer a long-term vision in laboratories. In January 2024, seven departments including the Ministry of Industry and Information Technology jointly issued the *Implementation Opinions on Promoting the Innovation and Development of Future Industries*, listing it as one of the top ten iconic innovative products. In January 2025, Beijing and Shanghai successively issued action plans for the innovation and industrial cultivation of brain-computer interface, clarifying the comprehensive clinical transformation of products by 2030.

However, compared with the speed of technological evolution, the pace of legal regulation is slow. Brain-computer interface directly intervenes in the brain, the most private human organ, and the derived risks of personal safety, neural information leakage and the dilemma of liability attribution in human-machine collaboration can no longer be properly addressed by the traditional legal paradigm. Between the two, the rational choice of regulatory path is particularly urgent.

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## 2. The legal picture of brain computer interface technology and the necessity of legal adjustment

### 2.1. The operation mechanism and legal characteristics of brain computer interface technology

The core of brain-computer interface is to bypass peripheral nerves and muscles and directly establish a brand-new communication and control channel between the brain and external devices. According to the degree of invasion to the brain in signal collection, the academic community generally divides brain-computer interface into three categories: non-invasive, semi-invasive and invasive. Non-invasive BCI collects electroencephalogram signals through scalp surface electrodes, with high safety but low resolution; semi-invasive BCI places electrodes on the epidural or cortical surface, with better signal quality; invasive BCI requires implanting electrodes into the cerebral gray matter through craniotomy, with the most accurate signals, but accompanied by high medical risks such as infection, bleeding, nerve damage and poor biocompatibility.

From the perspective of legal evaluation, technical details are not the focus of this paper. What is truly normative is the three key characteristics that distinguish brain-computer interface from other human-computer interaction technologies. First, direct intervention. The technology acts directly on the brain, the most private, sensitive and non-renewable human organ, and the depth of intervention is incomparable with any existing auxiliary equipment. Second, bidirectional interaction. Expanding from "brain-to-machine" signal reading to "machine-to-brain" reverse stimulation, and even higher-order "brain-to-brain" interconnection, the brain is no longer only a source of information, but also an object of external signal intervention. Third, identifiability and inferability of neural data. Raw electroencephalogram signals can form a "brain fingerprint" for individual identification, and after decoding and analysis, deep information such as emotional state, thinking preference, memory content and even political tendency can be further inferred.

### 2.2. The necessity of legal adjustment: From instrumental rationality to humanistic order

First, the shaking of the mind-body dualistic structure. The brain has long been regarded as the "last fortress" of consciousness, thought and emotion, and the traditional legal order therefore defaults that the spiritual field will not be directly invaded by external technologies [1]. However, the general-stage brain-computer interface will break the consistency between the "subjective self" and the "objective self" – mind-controlled objects expand self-consciousness from a single physical body to multiple external carriers, and consciousness cloning and brain networking further make "what constitutes me" an unresolved question [2]. When the body is no longer the only executor of will, the traditional personality right protection system constructed through the body is facing structural loosening. Second, the questioning of human subjective status. The traditional rights system takes "human being" as the preset logical starting point, but brain-computer interface technology may fundamentally shake this premise: when machines deeply intervene in decision-making, memory and emotion, human autonomy, personality identity and even the qualification as a rights subject need to be re-argued [3].

Therefore, the legal adjustment of brain-computer interface should not stop at instrumental safety control, but return to the value origin of "humanistic order". This value position constitutes the internal basis for the subsequent typological analysis of risks and the construction of regulatory paths in this paper.

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## 3. Analysis of legal risks and types of brain-computer interface technology

### 3.1. The risk of damage to personal rights and interests: The dual danger of physical integrity and mental integrity

In terms of physical integrity, invasive brain-computer interface requires implanting electrodes into the cerebral gray matter through craniotomy, which leads to significant medical risks. In addition to short-term damages such as bleeding and infection that may occur during surgery, long-term implantation of electrodes in the human body may also cause inflammatory reactions, skin erosion, abnormal bone growth, nerve function damage or immune reactions. Such risks can still be subsumed by the right to bodily integrity under Article 1003 and the right to health under Article 1004 of the *Civil Code* in systematic interpretation, and the relevant liability for compensation can also be determined with reference to the provisions on defective medical products in Article 21 of the *Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Medical Damage Liability Dispute Cases*.

What is more groundbreaking is the infringement of mental integrity by brain-computer interface. Such infringement does not lie in visible wounds at the physical level, but in implicit disorders at the neural network function level. Such infringement poses a fundamental challenge to the traditional framework of the right to health: on the one hand, infringement of mental integrity is often implicit and long-term, and the proof of damage formation and causal relationship cannot be properly addressed by traditional remedy paths; on the other hand, the traditional right to health protects the sound state of the physical and mental integrity, and it is difficult to accurately respond to the protection demand of the unique legal interest of "involuntary mental state change".

### 3.2. The risk of damage to the legal interests of neural information: The loss of spiritual privacy and personality autonomy

Neural information (or neural data) has three legally relevant characteristics that distinguish it from general personal information. First, identifiability. Raw electroencephalogram signals can form a "brain fingerprint", constituting biometric information comparable to fingerprints and genes. Second, inferability. Neural data can infer deep information such as emotional state, thinking preference, memory content, decision-making tendency, and even religious belief and political attitude after decoding and analysis, and such inference does not require combination with other data. Third, high sensitivity. Neural data is directly related to brain activities such as memory and thought, and is a direct carrier of subconsciousness that individuals do not want others to know [4]. Based on this, the academic community has generally advocated including it in the category of sensitive personal information and granting stricter protection rules than general personal information.

First, involuntary reading of spiritual privacy. Once the brain-computer interface is connected to the human brain, human thoughts can be scanned, read and monitored, and the user is virtually "running naked" under a searchlight. This reading has particularity not found in traditional privacy infringement: traditional privacy protection presupposes passive and secret behavioral patterns such as "prying, intruding, disclosing and publicizing", while neural data collection is often premised on the user's active acceptance of the device; traditional privacy protection protects the unexternalized internal information of individuals, while brain-computer interface directly exposes thought, the "last fortress", to the outside. Thus, the privacy protection established by Article 1032 of the *Civil Code* encounters dilemmas in application – the traditional principle of "reasonable expectation of

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privacy" is difficult to cover brain neural activities, and ex post remedies are difficult to meet the ex ante prevention needs of technical risks.

Second, decoding and abuse of neural data. Neural data faces security risks in all links of collection, storage and transmission: when hijacked by hackers, it may directly affect the use of equipment or even cause physical damage; when stolen secretly, users are highly likely to be unaware of the infringement of their rights and interests; when modified and input reversely, the normal treatment process, emotions and psychological experience of users are highly likely to be interfered and distorted. In addition, the industry has not yet formed unified standards for neural data processing, and the cross-subject flow and cross-scenario use of neural data further amplify the risk of abuse.

Third, neural discrimination and neuromarketing. If neural data is improperly used for non-medical purposes, "neuromarketing" and "neural discrimination" will breed – online platforms conduct precise personalized push based on this, aggravating the "information cocoons" and depriving individuals of independent choice space; insurance companies refuse insurance or increase premiums according to the disease tendency revealed by a policyholder's neural data, constituting a substantive infringement of equal rights and interests [5].

### 3.3. Autonomy of will and responsibility bearing risk: The accountability dilemma in human-machine cooperation

The disturbance to the authenticity of declaration of will can be divided into two levels. The first is the problem of "output of will": when paralyzed patients output their will to the screen through brain-computer interface, errors may occur in all stages of signal collection, conversion and algorithm processing, and it is necessary to carefully evaluate whether their externalized expression can accurately reflect their inner true meaning. The second is the problem of "generation of will": in the case of bidirectional brain-computer interface, external devices will feed back stimulation signals to the brain, directly affecting the user's emotions, judgments and even will itself, resulting in the state of "I don't feel like myself" reflected by users. However, in accordance with Articles 143 and 147 et seq. of the *Civil Code*, the balance between the judgment of the authenticity of declaration of will, the allocation of burden of proof and the protection of the reliance interests of the counterpart to the contract in the context of brain-computer interface has not been clearly answered by the current norms.

The dilemma of liability attribution for tort liability is more tricky. When damage mediated by brain-computer interface occurs, the attribution of act itself is difficult to clarify. Acts mediated by brain-computer interface are actually completed by human consciousness and algorithms together, with most of the process control completed by computers; under the framework of "brain-computer interface + artificial intelligence", brain-computer interface can even predict and act autonomously in advance according to the user's previous behaviors, further diluting human participation. Once damage occurs, it is difficult to externally identify "who" made the result – is it the user's subjective will? The algorithm's independent decision? Or the joint effect of the two?

The consequent chain problem lies in the diversification of liability subjects and the difficulty of proving causal relationship. After damage caused by brain-computer interface technology, the subjects who may bear liability include but are not limited to users, equipment manufacturers, algorithm writers, medical institutions and regulatory authorities; their liabilities are often causally related and cannot be simply evaluated in isolation. According to the current rules, damage results caused by multiple factors shall be borne by the relevant subjects jointly and severally; however, for sellers and medical institutions, they are not aware of the internal algorithm logic of brain-computer

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interface and are difficult to predict and prevent in advance, so bearing equal joint and several liability is not only unfair, but also may reversely inhibit the willingness of market entities to use this technology.

## 4. Evaluation of the responsiveness of the current legal framework and its deficiencies

### 4.1. Status quo of scattered supply and coverage of current specifications

At the level of basic civil law, Articles 1003 to 1004 of the *Civil Code* stipulate the right to bodily integrity and the right to health of natural persons, and Articles 1032 to 1034 respectively construct a dual protection mode of "privacy right + personal information" for privacy rights, private information and personal information protection. Articles 1219 and 1226 specially stipulate the informed consent in medical treatment and the obligation of medical institutions to keep confidential the privacy and personal information of patients. With regard to compensation for damages, Article 21 of the *Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Medical Damage Liability Dispute Cases* clarifies the liability for compensation of medical institutions, producers and sellers when defective medical products cause damage.

At the level of special legislation, Article 28 of the *Personal Information Protection Law* defines sensitive personal information with an open structure of "enumeration + etc.", and specially stipulates the special processing rules for sensitive personal information through Articles 28 to 32. The "separate consent" rule established in Article 29 and the impact assessment system in Article 55 can provide preliminary normative support for neural information processing. In addition, the *Regulations on the Supervision and Administration of Medical Devices* and the *Rules for the Classification of Medical Devices* bring brain-computer interface equipment into the regulatory framework of Class II or Class III medical devices.

At the level of ethical and industrial norms, the *Ethical Guidelines for Brain-Computer Interface Research* compiled by the Artificial Intelligence Ethics Subcommittee of the National Science and Technology Ethics Commission in February 2024, the *Measures for Ethical Review of Life Science and Medical Research Involving Humans* issued by the National Health Commission and other departments in 2023, and the *Measures for Ethical Review of Science and Technology (for Trial Implementation)* jointly issued by ten departments including the Ministry of Science and Technology in October 2023 constitute the basic framework for ethical review of brain-computer interface research. Among them, Articles 25 and 26 of the *Measures for Ethical Review of Science and Technology (for Trial Implementation)* establish a list system for science and technology activities with high ethical risks, and explicitly include "clinical research on invasive brain-computer interface for the treatment of neurological and mental diseases" into list management.

### 4.2. Triple performance of insufficient supply

First, insufficient supply in the dimension of subjectivity. Neural information lacks an independent legal status. Although Article 1034 of the *Civil Code* includes "biometric information" into the scope of personal information protection, it does not mention neural information as a new type; the enumerative provisions in Paragraph 1 of Article 28 of the *Personal Information Protection Law* also do not explicitly cover neural information [5]. This absence leads to the embarrassment of "putting new wine in old bottles" in neural information protection: traditional privacy right takes "unwilling to be known by others" as the subjective element, while the premise for individuals to

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use brain-computer interface is precisely "informed and consented", which makes brain privacy not fully conform to the subjective element preset of the existing privacy right [6].

Second, insufficient supply in the dimension of remedy. Traditional privacy right protection focuses on ex post remedies after rights infringement, while neural information infringement may be caused by "procedural violations" – such as failure to fulfill the obligations of "clear notification" and "written notice", violation of the "informed consent" rule, etc. The existing damage remedy measures are obviously not comprehensive enough in ex ante prevention, and it is difficult to cover the dual demand of "ex ante prevention + ex post remedy" unique to neural information protection. At the same time, traditional privacy infringement applies the principle of fault liability established in Paragraph 1 of Article 1165 of the *Civil Code*. However, under the discrete and hidden infringement patterns involving online platforms, it is very difficult to prove the fault of the actor, and the principle of fault liability is difficult to effectively punish privacy infringement in the context of brain-computer interface.

Third, insufficient supply in the dimension of responsiveness. The static characteristics of current norms are difficult to adapt to the rapid evolution of technology. On the one hand, although the *Ethical Guidelines for Brain-Computer Interface Research* clarifies the basic principles and general requirements for brain-computer interface research, it only generally states that "the scope of collected data and the authority of accessible personnel shall be approved by the ethics committee" for the data generated by brain-computer interface, and does not specify the specific rules for data collection and processing; the guideline also does not touch on the psychological problems, personality dignity issues and validity of civil legal acts arising from brain-computer interface users.

## 5. Systematic construction of legal regulation path of brain-computer interface technology

In view of the fragmentation and failure of current norms, the construction of regulatory path should not only stop at the revision of several provisions, but follow the three-stage logic of "right justification – norm improvement – regulatory innovation": first justify the independent status of neural information rights and interests at the personality right level, then improve the connection and application of civil law and personal information protection law at the specific rule level, and finally promote the collaborative innovation of ethical review, regulatory sandbox and cross-border governance at the regulatory model level.

### 5.1. The basis of rights theory: Neural information rights as a new right

The design of any specific rule needs to be based on an appropriate right theory. There are two ideas in the academic community on the legal positioning of "neural information rights and interests" in the context of brain-computer interface: the expansive interpretation theory attempts to subsume it within the traditional rights system, while the emerging right theory advocates confirming it as an independent personality right and interest. Integrating the strengths of both, this paper tends to justify based on the emerging right theory – but on the premise of strict legitimacy test to avoid the generalization of emerging rights.

The justification logic can be carried out in two steps. The first step is the substantive standard test of emerging rights: neural information rights and interests meet the three judgment criteria of complexity of object, richness of content and context, and uniqueness of protection demand. Its object covers privacy issues arising from brain data analysis, brain information related to personal physical health and mental state information, bearing complex legal interests of basic human rights attribute, general personality right attribute, privacy right attribute and personal information

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attribute; its content involves rich types such as the right to self-determination of neural information, the right to know, spiritual privacy right and mental integrity right, which cannot be covered by a single specific personality right.

The second step is the definition of the right core: based on the legal philosophical foundation of "consciousness autonomy", the specific content of neural information rights and interests can be roughly summarized into four items: cognitive freedom, spiritual privacy, mental integrity and psychological continuity. Cognitive freedom aims to protect individuals' control and free choice over their own psychological processes; spiritual privacy aims to protect private or sensitive information in the mind from unauthorized collection, storage and use; mental integrity emphasizes preventing unauthorized brain intervention and ensuring individuals' control over their own mental state; psychological continuity aims to protect the psychological basis of personal identity from unconscious and unauthorized changes by neural technology.

### 5.2. Standardization and perfection: Multi-level protection from privacy to sensitive personal information

First, at the basic civil law level, neural information should be included in the category of sensitive personal information through interpretation based on Article 1034 of the *Civil Code* and Article 28 of the *Personal Information Protection Law*. Paragraph 1 of Article 28 adopts an open structure of "enumeration + etc.", and the word "etc." reserves space for normative interpretation of the inclusion of neural information. On this basis, a special protection rule of "scenario-based + dynamic consent + systematic" can be constructed. Scenario-based protection classifies neural information horizontally – neural information in different scenarios such as disease diagnosis, equipment control, cognitive assessment and ability enhancement has significant differences in sensitivity and legal risks, and "one-size-fits-all" protection should be avoided [7]; dynamic consent protection breaks through the complex barriers of technological development vertically, requiring a new consent form for each subsequent specific research and use purpose after the initial consent, so as to realize the full-cycle protection of the subject of neural information rights.

Second, at the level of tort liability, the connection rules of product liability and medical damage liability should be improved. Brain-computer interface infringement is a typical multi-hand problem, and simple application of joint and several liability is unfair to sellers and medical institutions. In this regard, hierarchical allocation of liability should be carried out according to the actual control ability of each subject over the algorithm logic: producers and algorithm designers, as subjects with ultimate knowledge of the technical mechanism of equipment, bear heavier liability for product quality and safety guarantee; medical institutions mainly bear the duty of care in the process of medical operation; sellers bear reasonable intermediate review obligations. At the same time, reference can be made to the presumption of fault rule in Article 69 of the *Personal Information Protection Law*, where the information processor shall bear the burden of proof for its absence of fault.

Third, at the level of validity of declaration of will, two situations of "brain-to-machine" and "machine-to-brain" should be distinguished. For the one-way situation of "brain-to-machine", the declaration of will externalized by the user through brain-computer interface shall in principle be regarded as their true meaning; however, if the user or their close relatives can prove that the declaration of will is obviously inconsistent with their declaration of will under normal circumstances, it shall be deemed as untrue declaration of will. For the bidirectional situation of "machine-to-brain", since external signals are reversely input into the brain to interfere with the formation of will, further subdivision is required: if caused by brain-computer interface failure, the

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user can be deemed as coerced to claim revocation, and pursue tort liability against the manufacturer or medical institution; if caused by third-party hacker intrusion, liability shall be pursued against the hacker, but the reliance interests of the counterpart to the contract shall also be protected, and the user shall first bear liability for breach of contract to the counterpart to the contract, and then resolve disputes with the third party in accordance with the law.

### 5.3. Regulatory innovation: Synergy of ethical review, regulatory sandbox and cross-border governance

First, the prepositive function of ethical review. Brain-computer interface is a high ethical risk field, and the *Measures for Ethical Review of Science and Technology (for Trial Implementation)* has explicitly included "clinical research on invasive brain-computer interface for the treatment of neurological and mental diseases" into the list of science and technology activities with high ethical risks. On the basis of the existing three-level review system of "laboratory – hospital – enterprise", ethical review before decision-making should be taken as the core link – including not only the safety review of biocompatibility and technical parameters of brain-computer interface equipment, but also the substantive assessment of patients' cognitive ability and degree of informed consent; at the same time, a hierarchical protection and progressive desensitization mechanism should be established, equipped with an emergency stop function after using brain-computer interface equipment, and granting patients the right to terminate and withdraw at any time.

Second, the introduction of the regulatory sandbox model. First proposed by the UK Financial Conduct Authority in 2015, the "regulatory sandbox" aims to balance the contradiction between technological innovation and regulatory lag through a loose testing environment. This model is characterized by differentiated management of "one policy for one enterprise", dynamic ex ante review and full-process information reporting, and is particularly suitable for the regulatory needs of the highly innovative and high-risk unknown field of brain-computer interface.

Third, the connection of cross-border governance. Chile took the lead in amending the constitution to protect "brain activity and the information generated thereby" in 2021, and established five principles of neural rights through the *Neuroprotection Act*; in August 2023, the Supreme Court of Chile ruled on the case of Emotiv collecting neural data without informed consent, setting a precedent for the judicial protection of neural rights. Although China should not copy Chile's path of "constitutionalization of neural rights", it should draw on its legislative concept of elevating neural rights to the level of constitutional protection under the tone of "active support and prudent regulation", and realize concretization through the coordination of departmental laws [8]. At the same time, China should promote the formation of international consensus on neural rights protection and the construction of transnational data protection mechanisms to avoid falling into a regulatory island in global technological competition.

## 6. Conclusion

The two-layer structure of "risk typology – regulatory systematization" proposed in this paper is precisely an attempt to seek a dynamic balance between the two dilemmas: based on the *Civil Code* and the *Personal Information Protection Law*, justify neural information rights and interests as emerging personality rights and interests, supplemented by scenario-based special rules, hierarchical allocation of liability, regulatory sandbox and other innovative tools, so that the law can respond to technological evolution in a "flexible and dynamic" manner. As some scholars have pointed out, no matter how considerable economic, political and social values brain-computer interface can create, it

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must first stick to the bottom line of protecting human beings. Although the mind-body dualistic structure of human beings has been shaken by technology, "being human" as the logical starting point of legal order still needs to be regarded as the fundamental basis of all regulatory paths.

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