Neuroethical Challenges of Brain-Computer Interface Regulations: A Comparative Analysis of the U.S., EU, and China

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Abstract

The rapid growth and real-world applications of brain-computer interfaces (BCIs) in medicine have given rise to a range of ethical and legal challenges. Despite various policy and regulatory studies conducted in response, there remains a lack of systematic research on BCIs regulation worldwide. This article introduces the fundamentals of BCIs and analyzes four ethical issues that emerge with their application: safety risks, privacy violation, individual autonomy, and social inequality. It then examines the current regulation of BCIs in the United States (U.S.), the European Union (EU), and China. This involves comparing their differences and analyzing their shortcomings. The study finds that the existing regulatory frameworks fail to adequately address these four ethical aspects. In response to this problem, it is recommended to establish a diverse regulatory toolbox that facilitates collaboration among governments, industry, independent agencies, civil society, and international organizations. This toolbox should adopt targeted strategies for the four primary concerns identified: implementing tiered security standards, creating neural data classification systems, clarifying informed consent procedures, and ensuring equal access to BCIs. By integrating these precise measures, the toolbox aims to address the multifaceted challenges of BCIs comprehensively and support their ethical and sustainable development.

Keywords: brain-computer interfaces (BCIs), technical safety, privacy protection, informed consent, social inequality, regulatory toolbox

1 INTRODUCTION

Brain-computer interfaces (BCIs) are systems that enable direct communication between the brain and external devices, allowing control or interaction through neural activity (Lebedev & Nicolelis, 2006). The main goal of BCIs is to assist individuals with neuromuscular disorders, such as ALS, cerebral palsy, stroke, or spinal cord injury (Shih et al., 2012). Being employed in medical and therapeutic applications, BCIs offer rehabilitation possibilities for patients with neurological diseases, while its risks, particularly in a long term perspective, are mostly unknown (Bernal et al., 2021).

The last decade has witnessed increasing scholarly attention to neuroscience achievements and attendant ethical problems (Petoft & Abbasi, 2020). Safety issues, privacy violations, human autonomy problems, and social inequality are the primary concerns raised by BCIs. While BCIs enable brain-controlled communication and movement, they also pose safety risks such as bleeding and infection (Chen, 2023). Additionally, BCIs also raise privacy concerns due to their potential to monitor and alter brain activity (Naufel & Klein, 2020). In particular, the application of BCIs may affect users' sense of agency (Vlek, et al., 2014), which complicates the attribution of responsibility in infringements (Schönau et al., 2021). Furthermore, BCIs may exacerbate social inequality and widen class divides by enhancing human capabilities (Gordon & Seth, 2024). Given these issues, it is essential to develop coherent policies for responsible BCI development (Schmid et al., 2021). This leads to the critical question: Are current regulations adequate to address emerging ethical concerns surrounding BCIs? Further investigation is needed to assess existing regulations and provide a basis for future strategies.

This research examines the regulations of three major regions at the forefront of BCIs: the United States (U.S.), the European Union (EU), and China. These regions were selected due to their technological leadership and diverse regulatory approaches. The study provides a comparative analysis of global responses to BCIs, identifying regulatory gaps and proposing solutions to ethical challenges.

The article is structured as follows: Part II reviews the international progress of BCIs; Part III explores ethical issues of BCIs, including risks in safety, privacy, autonomy, and social equality; Part IV compares current regulations in the U.S., EU, and China; and Part V presents a regulatory toolkit to address the identified issues.

2 FRONTIERS OF BCIS RESEARCH AND PROJECTS

2.1 The Development of BCIs

In the 1970s, Jacques J. Vidal first proposed the concept of brain-computer interface (BCI), using electroencephalogram (EEG) signals for communication between humans and machines (Vidal, 1973). BCIs enable users to control external devices via brain signals, assisting paralyzed patients in regaining movement through prosthetic limbs (Mak & Wolpaw, 2009).

Technological advances have led to key innovations in BCIs. In 2013, the U.S. Food and Drug Administration (FDA) approved the NeuroPace RNS System, the first BCI device for treating partial epilepsy. In 2019, Neuralink developed an advanced

signal acquisition system for BCIs, which broke the channel count limits and improved the accuracy of targeting specific brain regions (Musk, 2019). Current research in BCIs is focused on restoring physical functions in individuals with disabilities, such as enabling communication for those who can no longer speak (Willett et al., 2021). China has also made strides in the field of BCIs. The newly developed BCIs enable the implantation of flexible electrodes into the brain via a minimally invasive procedure, thus eliminating the need for a craniotomy (Tang et al, 2023, Wang et al, 2023). In 2020, Zhejiang University successfully completed China's first clinical study of implantable BCI, enabling a 72-year-old paraplegic patient to precisely control external machinery with brain signals (Si et al, 2023).

Currently, BCI research is exploring not only the treatment of neurological diseases but also how the brain can record, process, utilize, store, and retrieve vast amounts of information at the speed of thought. However, the application of BCIs requires caution, as commercial interests may push premature neurotechnologies to market (Justo & Erazun, 2007), highlighting the need to uncover and address ethical concerns related to BCIs.

2.2 Projects of BCIs in U.S.- EU-China

As early as 1989, the U.S. government designated the last decade of the 20th century as the "Decade of the Brain". In 2014, the U.S. launched the BRAIN Initiative to explore the working mechanism of brain and develop new treatments for brain diseases (U.S. National Institutes of Health 2014). In 2019, the Advisory Committee to the NIH Director endorsed a report named "The BRAIN Initiative and Neuroethics" (U.S. National Institutes of Health 2019). This document created a set of neuroethics guiding principles, which emphasize the importance of assessing safety and protecting the privacy and confidentiality of neural data.

The Human Brain Project (HBP) is the largest brain science project in Europe, involving over 500 scientists and engineers from over 140 institutions (Human Brain Project 2023). In 2020, HBP shifted focus to three core scientific areas: brain networks, their role in consciousness, and artificial neural nets. HBP has also spurred neuroscience competition in the U.S. and China (Frégnac & Laurent, 2014). However, ethical concerns, especially regarding consent and privacy, have been highlighted since its inception (Rose, 2014).

The China Brain Project, entitled "Brain Science and Brain-Inspired Intelligence", is formulated as a 15-years plan (2016–2030) (Poo et al., 2016). In 2017, the State Council of China proposed Development Planning for a New Generation of Artificial Intelligence to study brain-like intelligence computing theories (Chinese State Council 2017). In 2021, the Ministry of Science and Technology officially announced the annual application guidelines for the major "Brain Science and Brain-like Research" project, involving 59 research fields and directions. Chinese tech companies are venturing into non-invasive BCIs, fostering the growth of several BCI startups, like Neuracle Tech, BrainCo and BrainUp. The BCI industry in China is thriving, with a developing industrial chain (China Electronics Standardization Institute 2021).

In general, the U.S., the EU, and China are at the forefront of BCIs development, making the ethical review of BCIs particularly urgent in these regions. Therefore, before delving into the current regulations, it is necessary to conduct a more systematic discussion of the ethical concerns associated with BCIs.

3 ETHICAL CONCERNS OF BCIS

3.1 Health and Safety Risks

BCIs have the potential to impact users' physiological health and raise safety concerns. Existing research suggests that BCIs may cause some damage to the human body. MRI-based BCIs generate strong magnetic fields, potentially affecting neurological and cardiovascular functions (Birbaumer & Cohen, 2007). Steady-state visual evoked potential (SSVEP) BCIs may trigger epilepsy in long-term users (Bakardjian, Tanaka, & Cichocki, 2010). However, predicting these risks remains difficult due to ongoing technological development.

Additionally, the implantation of BCIs also presents safety issues. Although implanted devices are vital for capturing neuronal activity in invasive BCIs, the implantation procedure may inevitably disturb human tissue (Coin, Mulder, & Dubljević, 2020). During the implementation process, users may encounter various physical safety risks, including immune system rejection, infection of tissues, and blood vessels (Jawad, 2021).

Furthermore, the long-term effects of BCIs deserve attention. Prolonged neural compression from implanted BCIs may cause infections and glial injury (Schneider, Fins, & Wolpaw, 2012). Long-term BCI users may also experience brain plasticity issues, which could lead to irreversible effects (Tamburrini & Mattia, 2011). Over time, implanted components suffer from problems like corrosion, aging, and site movement, heightening the risk of malfunctions and errors (Hildt, 2011).

Security threats are another major issue. Computer hackers with technical expertise may hack into BCIs and manipulate users' neural activity (Thompson, 2021). Given BCIs' deep integration with the nervous system, cyberattacks could have severe consequences (Farahany, 2015).

3.2 Privacy Violation Issues

BCIs can extract sensitive information from users' brains, heightening concerns about privacy and data protection. They provide vast amounts of personal information, including health status, emotions, and personality traits (Lebedev & Nicolelis, 2011). Providers of BCIs may collect these data without users' awareness or consent, potentially for purposes beyond what was agreed (Vlek, et al., 2012). Research settings, especially in human trials of BCIs, could inadvertently expose private data (Klein, 2016). Moreover, remotely monitored chips in BCIs increase the risk of privacy breaches (McGee & Maguire, 2007).

Additionally, BCIs are vulnerable to cyberattacks, which can compromise personal data during storage or transmission (Schlaepfer & Fins, 2010). Direct transmission of brain signals to computers makes them susceptible to hacking. It has been shown that hackers may exploit BCIs to steal users' sensitive data, including

PINs or bank details (Ienca & Haselager, 2016). Through technical means, hackers can directly infiltrate the neural processes of BCI users to extract confidential or sensitive information. With the increasing fidelity of BCI data, there is a potential risk of exposing more sensitive information (Müller & Rotter, 2017). Enhancing privacy protection has become an unavoidable issue in the advancement of BCIs.

3.3 Problems of Autonomy and Responsibility

BCIs also raise concerns about human autonomy, agency and responsibility. Algorithms in BCIs can analyze and influence users' emotions, thoughts, and decisions by processing vast neural data (Arendt, Scherr, & Romer, 2019). These issues become more pressing when BCIs autonomously modify algorithms through continuous, opaque processes (Reilly, 2020). The integration of intelligent algorithms and BCIs may blur the user's sense of agency, particularly when control shifts implicitly from the user to the intelligent device (Haselager, 2013). This uncertainty raises questions about whether actions performed through BCIs genuinely originate from the user's own thoughts or are influenced by algorithms (Aggarwal & Chugh, 2020). Similar ambiguity in tort and criminal cases could lead to significant controversy over the attribution of legal responsibility.

Additionally, "brain-hacking" threatens autonomy by allowing unauthorized monitoring or manipulation of psychological experiences (Yuste et al., 2017). Illicit interference with neural computations could alter users' decisions or even endanger their lives (Kellmeyer, 2021).

While concerns over BCIs are universal, regional responses are various based on cultural, legal, and social contexts. In the U.S., a strong tradition of individual rights shapes discussions on BCIs, emphasizing personal freedom, autonomy, and safeguards against misuse. The EU, guided by regulations like the General Data Protection Regulation (GDPR), prioritizes data protection and individual autonomy over personal data. China, characterized by rapid technological advancement and a focus on collective welfare, may seek a balance between individual rights and broader societal considerations in the development of BCIs.

3.4 Difficulties of Social Equality

In the near future, BCI research may shift towards enhancing human biological abilities, potentially exacerbating disparities in mental capacity, resource allocation, and social status (Nandwani et al.,2024). This raises the ethical challenge of balancing individual rights with the common good. Given the typical personal differences among BCI users, improvements for one user may not necessarily benefit others. As such, determining whether to allocate public resources for system upgrades could be challenging (Richman, 1989).

In this context, BCIs present unique challenges across different regions. In the U.S., the privatized healthcare system may exacerbate disparities in BCI access based on income, with wealthier individuals gaining early access to innovations (Chien, 2022). The EU's inclusive healthcare and education systems promote more equitable BCI distribution but require careful management of public funding. In China,

disparities in BCI access may arise due to differences in urban and rural technological infrastructure.

4 CURRENT REGULATIONS OF BCIS

In response to these concerns, it is vital to assess if the current regulatory frameworks can handle the new risks of BCIs. Currently, direct regulation of BCIs remains limited, with most guidelines rooted in medical ethics. The U.S., the EU and China are the leading regions in BCIs regulation, indicating international trends in this area. The following sections will analyze their regulatory frameworks, highlighting key distinctions and potential deficiencies likely to arise from the evolving state of BCIs.

4.1 Regulation of BCIs in the U.S.

The regulation of BCIs in the U.S. operates at both federal and state levels, creating a decentralized and multi-layered framework.

At the federal level, multiple agencies share oversight responsibilities. The Food and Drug Administration (FDA) classifies BCIs as medical devices under Code of Federal Regulations (CFR), focusing on their safety and effectiveness. The Federal Trade Commission (FTC) monitors marketing practices under Section 5 of the FTC Act, aiming to prevent deceptive advertising related to BCIs (Blank, R. H., 2023). The Consumer Product Safety Commission (CPSC) primarily focuses on the physical safety of BCIs to ensure they do not pose harm to users. However, there is no specific federal regulations for BCIs, and the neural data can only be treated as conventional health data under Health Insurance Portability and Accountability Act (HIPAA). This oversight gap leaves users exposed to risks such as algorithmic manipulation and unauthorized neural data use (Bublitz, 2013).

State-level initiatives have introduced novel regulatory approaches. In 2021, Minnesota's House Bill No. 424 established neural rights in its amendment, banning cognitive manipulation and securing mental integrity (Minnesota State Legislature 2021). While aligning with emerging neuroethics research, the Bill lacks provisions for subconscious data extraction, third-party data use, and liability for device malfunctions. In 2024, Colorado amended its privacy act to include biological data, such as neural data, within the category of sensitive data (Colorado General Assembly 2024). Unlike Minnesota's focus on cognitive manipulation, Colorado emphasizes commercial data governance, reflecting its tech-sector influence. However, its protections do not extend to non-commercial research BCIs and overlook the dual nature of neural data as both medical and behavioral information. While the regulations in Minnesota and Colorado exemplify state-level innovation, their narrow scopes underscore the need for federal harmonization.

Overall, BCI regulation in the U.S. remains fragmented. While state initiatives represent steps forward, their limited scope and enforcement challenges highlight the need for a national strategy that balances innovation with protections for human rights.

4.2 Regulation of BCIs in The EU

The EU's regulatory approach to BCIs is anchored in a layered legal framework that prioritizes data protection, human rights, and ethical accountability. Although there is no specific law for BCIs in Europe, various data protection regulations provide substantial protection for BCI users.

The Data Protection Directive (Directive 95/46/EC) set general rules for data privacy across both public and private sectors, laying the foundation for later data protection laws (Greenberg, 2019). In 2018, the General Data Protection Regulation (GDPR) replaced earlier frameworks, focusing on practical and comprehensive data protection (Kuner, 2012). The GDPR is crucial in protecting neural data, requiring risk assessments, informed consent, and greater control for users over their data. However, challenges remain. Neural data is not explicitly classified under the GDPR, creating interpretive difficulties since its sensitivity goes beyond conventional biometric data (Rainey et al., 2020). Anonymization, central to GDPR exemptions, does not fully address the risk of reidentification, as neural data often contains unique, traceable patterns(Finn et al., 2015, Dove & Phillips, 2015). Although anonymization techniques reduce the likelihood of information leakage, they do not fully ensure the safety and privacy of BCI users (Parker & Bull, 2015). This gap highlights the need for updated legal interpretations or additional guidelines to better align with neurotechnological developments.

Other regulations, such as the EU Charter of Fundamental Rights (CFR) and the European Convention on Human Rights (ECHR), protect privacy and autonomy, offering ethical safeguards against discriminatory or coercive BCI use. The Medical Devices Regulation (MDR) applies to BCIs considered medical devices, ensuring they meet safety and effectiveness standards. However, these rules remain fragmented, and greater regulatory harmonization within the EU could help balance innovation with rights protection.

In summary, EU regulations protect the data rights of BCI users, but lack tailored rules for neural data risks. Updated legislation or clearer legal interpretations are crucial for enhancing protection while promoting innovation in neurotechnology.

4.3 Regulation of BCIs in China

China's regulatory framework for BCIs encompasses personal data protection laws, biomedical regulations, and ethical guidelines, with the 2021 Personal Information Protection Law (PIPL) serving as the cornerstone.

Although the PIPL does not specifically mention neural data, it defines sensitive personal information as information that could threaten a person's dignity or safety if disclosed (Standing Committee of the Thirteenth National People's Congress of the People's Republic of China 2021). This definition logically includes neural data since it can reveal sensitive details like health status, religious beliefs, and emotions.

Based on this legal interpretation, neural data is subject to the most stringent protections under the PIPL, including mandatory explicit consent and enhanced security measures. However, obtaining meaningful consent from BCI users remains a challenge. BCIs often collect data passively and continuously, making it impractical to obtain repeated, explicit user approval over time. The PIPL requires clear

disclosure of data usage, but real-time data processing in BCIs complicates transparency, as users may not fully grasp how their neural data is processed.

Furthermore, the PIPL requires transparency in automated decision-making and permits users to opt out. Yet, the real-time feedback systems in BCIs make it hard to distinguish between automated and human-driven decision-making. Additionally, withdrawing consent for automated functions may disrupt core BCI operations, limiting user control.

Beyond the PIPL, several medical laws partially apply to BCIs, such as the Biosecurity Law and the Measures for the Administration of the Clinical Usage of Medical Devices. The former mitigates biosecurity risks linked to BCIs, while the latter standardizes clinical protocols, ensuring safety and efficacy. Ethical guidelines, including the Guidelines for Ethical Research on Brain-Computer Interfaces, further emphasize human rights, risk minimization, and ethical compliance in BCI development.

Despite these measures, gaps persist. Regulatory fragmentation between data privacy, biomedical oversight, and ethical guidelines complicates enforcement. China's regulatory approach, while robust in structure, requires tighter alignment between data protection, ethical governance, and sector-specific regulations to balance innovation with fundamental rights.

4.4 Comparison and Analysis Of Regulation In Three Regions

Generally, the U.S., EU, and China each have region-specific regulations for BCIs. The most pertinent regulations from these regions are listed in Table 1.

Table 1. Key regulations related to BCIs in the U.S., the EU, and China

Region	File Name	Main Content Related to BCIs
United States (U.S.)	Minnesota House Bill No. 424	It proposes a series of individual rights related to neurotechnology.
	Colorado Privacy Act (CPA)	It includes biological data, such as neural data, within the category of sensitive data.
	New York Assembly Bill 3196	It proposed a statewide pilot program for BCIs in homes.
	Code of Federal Regulations (CFR)	It classifies BCIs as medical devices and sets standards for their safety, effectiveness, and marketing.
	Federal Trade Commission Act	It regulates BCI marketing to prevent deceptive claims about safety, function, and benefits.
	Consumer Product Safety Act (CPSA)	It safeguards consumers from unreasonable physical risks associated with products, including BCIs.
	Health Insurance Portability and Accountability Act(HIPAA)	It ensures the privacy and security of neural data in healthcare applications.

	The Privacy Act	It ensures data protection and compliance in BCI regulation by governing personal information use.
	The American Data Privacy and Protection Act (ADPPA)	It could contribute to BCI regulation by setting strict data privacy and security standards for data processing.
European Union (EU)	Regulation (EU) 2018/1725 of the European Parliament and of the Council	It outlines the legal requirements for the processing of personal data, including neural data in BCIs.
	General Data Protection Regulation(GDPR)	It establishes the guidelines and standards for data protection within the EU, which are also applicable to neural data.
	The European Convention on Human Rights(ECHR)	It may influence BCI regulation by ensuring compliance with human rights standards, particularly regarding privacy, autonomy, and freedom from discrimination.
	Charter of Fundamental Rights of the European Union(CFR)	It can guide BCI regulation by ensuring ethical standards, fundamental rights protection, and legal accountability in neurotechnology use.
	EU Treaty	It offers a legal basis for harmonizing BCI regulation while ensuring ethical and data protection compliance.
	The Medical Devices Regulation (MDR)	It may play a key role in regulating BCI by ensuring safety, efficacy, and compliance with medical standards.
China	Personal Information Protection Law of the People's Republic of China(PIPL)	It can strengthen BCI regulation by enforcing strict data protection, consent requirements, and cross-border data transfer restrictions.
	Measures for the Ethical Review of Biomedical Research Involving Humans	It may be instrumental in BCI regulation by ensuring ethical oversight and protecting human participants.
	Measures for the Administration of Clinical Use of Medical Devices	It sets out guidelines and procedures for the clinical use of medical devices, including BCIs.
	Biosecurity Law of the People's Republic of China	It proposes a series of rules to prevent and address biosecurity risks, including those affecting BCIs.
	Opinions on Strengthening the Ethical Governance of Science and Technology	It outlines five ethical principles for new technology, including BCIs.
	Guidelines for Ethical Research on Brain-Computer Interfaces	It stipulates the basic principles and specific ethical rules of BCI researches.

Pertaining to the four legal aspects of BCIs in Part III, the U.S., the EU, and China have various regulation with distinct focuses. A detailed analysis of the table is presented as follows.

4.4.1 Safety Regulation

BCI regulations in the U.S., EU, and China reflect distinct legal priorities but share critical gaps. The U.S. maintains fragmented oversight through medical device and data protection frameworks, struggling to address the unique risks of neurodata. The EU's GDPR focuses on privacy through strict data limits but neglects dynamic neural interpretation challenges. China's state-driven governance emphasizes societal security through strict pre-market approvals. However, all regulations face key challenges. Users may not fully understand the risks of sharing neural data, making informed consent unreliable. Meanwhile, cross-border neural data transfers create legal loopholes, making accountability unclear. In addition, present approval systems fail to address risks from AI-driven updates after deployment. More importantly, current regulations treat BCIs as standalone devices rather than tools that reshape brain functions over time. To close these gaps, global cooperation is needed, combining flexible risk management with clear protections for neural data and human rights.

4.4.2 Privacy Protection

The U.S., the EU and China adopt distinct regulatory approaches to privacy protection in BCIs, each with systemic gaps. The U.S. relies on fragmented state-level laws, such as The Minnesota Bill, lacking a unified federal framework. This inconsistency leaves gaps in protecting neural data from corporate influence. The EU's GDPR enforces strict consent rules and broad data protections, but it does not explicitly classify neural data, limiting its effectiveness (Sommaggio et al., 2017). China's PIPL sets strict conditions for information processing, yet vague algorithmic oversight allows compliance loopholes. These gaps create risks in cross-border data transfers and user control. More critically, none of these systems fully address BCI-specific challenges, such as the sensitivity of real-time neural data, difficulties in securing meaningful consent, and risks from dual-use neurotechnologies. Without stronger international cooperation and clearer regulatory measures, existing frameworks will struggle to protect neural privacy in this rapidly evolving field.

4.4.3 Individual autonomy

The U.S., EU, and China exhibit distinct approaches to BCI user autonomy. The U.S. prioritizes explicit neural rights through decentralized state laws, yet lacks federal coordination and clear enforcement measures. The EU grounds protections in human dignity under Article 3 CFR but offers no BCI-specific operational rules, relying ambiguously on GDPR's data principles. China's PIPL focuses on restricting automated decisions, framing user autonomy as data control under state-centred governance rather than neurocognitive liberty. All three systems share critical flaws: vagueness in defining technical compliance (e.g., neural data boundaries), weak enforcement against corporate exploitation, and reactive rather than preventive safeguards for emerging neurotechnological harms. They also fail to address real-time neural manipulation risks, favoring abstract rights over practical safeguards. A

globally unified standard is needed—one that combines ethical clarity with strong enforcement to ensure both user autonomy and accountability in BCI governance.

4.4.4 Social equality

Regarding social equality issues in the field of BCIs, the U.S., the EU, and China have different governance approaches. The U.S. employs market-driven, sector-specific regulations, such as FDA oversight, which prioritize innovation but neglect disparities in access to cognitive enhancement. The EU emphasizes ethics in data protection, but inconsistent national policies weaken efforts to address BCI-related inequalities. China promotes fairness through state-led ethical guidelines, which, despite lacking enforcement tools, reflect a global pattern where non-binding guidelines outpace concrete legislation. Common critical gaps persist: reactive policy-making fails to address cost-driven access barriers. None of these systems effectively balance technological progress with fair access, increasing the risk of deepening socioeconomic divides as BCIs advance. Addressing these shortcomings requires proactive legal frameworks that prioritize equity, ensuring that neurotechnologies benefit all of society rather than reinforcing existing inequalities.

5 BCI REGULATION: A WAY FORWARD

Analyses of U.S., EU, and Chinese regulations suggest that current frameworks may not fully address the risks associated with BCIs. Effective management of emerging technologies requires a multi-dimensional approach (Hankin & Read, 2016), shifting from rigid 'command and control' strategies to 'responsive regulation' that allows for flexibility based on the specifics of the technology (Gunningham, 2012). Lessons from nanotechnology suggest that industry and civil society can proactively mitigate technological risks alongside governments (Malakar, Lacey, & Bertsch, 2022). In view of the collaborative governance model of nanotechnology, a regulatory toolbox should be developed that integrates multiple regulators and tailored measures for BCIs.

5.1 Establishing BCIs regulatory toolbox

Regulation of BCIs needs to unite efforts from governments, industry, independent organizations, civil society, and international bodies. Therefore, a structured regulatory toolbox should be established, to bring together views from various stakeholders. The toolbox should focus on the following aspects.

5.1.1 Government Adaptability

Governments should prioritize enhancing the adaptability and foresight of regulatory frameworks. Given the rapid evolution and interdisciplinary nature of BCIs, the transition from static regulations to a dynamic framework is critical. Adaptive regulation, such as regulatory sandboxes, could balance innovation with risk assessment (Ranchordas & Vinci, 2024). Additionally, smart regulatory platforms using big data and AI can further enhance precision in monitoring technological changes (Zetzsche et al., 2017).

5.1.2 Industry Self-Regulation

The private sector plays a significant role through self-regulation and collaboration. Cross-industry alliances should be built to develop common standards and best practices for new technologies (Adobor, 2011). Incentive mechanisms, such as tax breaks for companies excelling in data privacy, can further promote adherence to ethical standards. Blockchain-based regulatory tracking also enhances transparency and ethical compliance (Allena, 2020).

5.1.3 Independent Institutions

Independent institutions, such as public-private research labs, can stress-test new BCIs for ethical and legal risks (Battisti, 2014). Additionally, independent ethical review bodies may also serve as neutral arbitrators in BCI-related disputes, developing standardized ethical assessment frameworks for evolving technologies. Responsible innovation agreements between independent institutions, companies, and governments should clearly define safety, accountability, and risk mitigation strategies (Voegtlin & Scherer, 2017).

5.1.4 Public Involvement

Civil society groups, including non-governmental organizations (NGOs) and advocacy groups, can push for regulation of BCIs through public opinion. These public groups also play a vital role in driving awareness and educating the public on BCI-related issues. They should actively provide diverse feedback in the early stages of BCI regulation, ensuring the latest standards reflect diverse social needs.

5.1.5 International Cooperation

International organizations could work together to establish a cross-border neurotechnology regulatory network, reducing regulatory fragmentation and compliance gaps worldwide. Such regulatory networks should involve different countries to harmonize national standards and ensure ethical consistency (Verdier, 2009).

5.2 Regulation of Technical Safety

Ensuring technical security is a top priority in the development of BCIs, given their non-negligible impact on human health and vulnerability to cyberattacks.

5.2.1 Risk-Based Safety Evaluations

The regulation of BCIs should start with a risk-based approach, where safety evaluations are stratified based on the degree of invasiveness of BCIs. Invasive BCIs involving surgical implantation should be subject to the most stringent standards, followed by semi-invasive and non-invasive BCIs. Safety criteria must evolve with technological advances and clinical evidence. In addition, penalties should be commensurate with both the harm caused and the regulatory violations.

5.2.2 Lifecycle Security Regulation

To mitigate risks, safety oversight should extend across the entire technology lifecycle of BCIs, from the initial design phase to post-market surveillance. Strict protocols must be followed for safe operation and removal, while continuous safety monitoring is essential to address long-term effects of BCIs. Device providers must be prohibited from disabling devices without user consent, protecting against unauthorized manipulation or abandonment.

5.2.3 Self-Regulation on Algorithm Transparency

Industry associations should collaborate with regulators to establish safety and transparency standards for BCI algorithms. Regulators can mandate that BCIs providers should "label" their algorithms with key details such as provider information, technical standards, and data protection protocols (Yi, 2021). This approach improves traceability, reduces information asymmetry, and fosters accountability and trust.

5.2.4 Specialized Regulatory Agencies

Governments should establish dedicated regulatory bodies for BCIs, drawing from frameworks governing high-risk technologies, like the International Commission on the Clinical Use of Human Germline Genome Editing. These agencies would oversee certification, enforce adaptive safety standards, and conduct continuous risk assessments, ensuring ethical and technical compliance. By integrating interdisciplinary expertise, they can proactively address emerging challenges in BCI development and deployment.

5.2.5 Public Engagement and Oversight

A robust BCI regulatory framework necessitates proactive public engagement and independent oversight. Establishing an interdisciplinary advisory body, akin to Google's Advanced Technology External Advisory Council (ATEAC), should integrate expertise from medicine, AI, neuroscience, law, and ethics. This institution should bring together a variety of professionals to assess the security levels and technical risks of BCIs in advance, and make recommendations on the application of BCIs accordingly.

5.3 Personal Information Protection

The expanding adoption of BCIs and the escalating volume of collected data underscore the pressing need for robust personal information protection. To address the new challenges, future BCIs regulations should focus on the following areas.

5.3.1 Standardized Information Processing Procedures

Governments should develop standardized procedures for processing personal information from BCIs. Parties processing this information should clearly disclose the purpose, method, and scope of data use and obtain explicit consent from users. For sensitive information like neural data, separate consent and official approval are

required. Commercial use of neural data should be explicitly prohibited to prevent exploitation, and users should retain the right to withdraw consent at any time.

5.3.2 Classification of Neural Data

A structured classification of neural data is essential, categorizing it into public, general, and special data. Public data should follow predefined access protocols, while private data remains user-controlled. Based on the sensitivity of the data, private data can be further divided into general data and special data. Special data, which impacts personal dignity or security, requires stricter regulations. General data, with less risk, can follow standard protocols. In cases of public security threats, state access may be justified under stringent legal constraints.

5.3.3 Preventing Malicious Information Writing

Strict regulations must govern BCI data writing, requiring prior regulatory approval to activate this function. BCIs providers should implement continuous monitoring systems to detect and prevent malicious alterations. In addition, a traceability system for information writing should be established to track data input origins. Providers should encrypt the input data and submit regular reports to authorities to address any security threats promptly.

5.3.4 Industry-wide Standards and International Guidelines

Apart from formal regulations, soft tools can also provide a flexible approach to protecting users' rights. Multiple parties (e.g. BCIs developers, potential users, and research management organizations) should collaborate to establish industry-wide standards and clarify the responsibilities of all involved entities. A comprehensive self-regulatory system would ensure that BCIs operate within ethical and technical standards. Furthermore, international cooperation is vital in establishing shared ethical norms for neurotechnology, facilitating global governance of this emerging field.

5.4 Safeguards for Informed Consent

Informed consent is a fundamental right that ensures individual autonomy, especially in the context of emerging technologies like BCIs. Regulation in this area should pay attention to the following aspects.

5.4.1 Dynamic Informed Consent Systems

As BCIs involve complex interactions between human cognition and machine intelligence, the associated risks must be disclosed to users before application. However, given the unpredictable nature of BCIs, a static consent model may fall short. A dynamic informed consent framework should be adopted, ensuring continuous user engagement. This model would provide real-time updates on technological changes, allowing users to reassess and reaffirm consent throughout the BCI lifecycle, thereby enhancing autonomy, transparency, and ethical oversight.

5.4.2 Managing Expectations of BCI users

A key aspect of informed consent is ensuring users grasp the full implications of BCI use. The current media overstatement has increased the public expectation of BCIs (Gilbert et al., 2019). To mitigate this risk, professionals, BCIs experts, and regulators should provide accurate information to correct misconceptions and facilitate informed decision-making. For those with cognitive impairments, authorized agents should be appointed to make decisions about the use of BCIs, mirroring ethical guidelines for human trials (Zeng, Sun, & Lu, 2021).

5.4.3 Liability Frameworks for BCIs Infringements

While informed consent is a preventive measure, it must also be backed by strong post-infringement liability frameworks. The complexities of neurotechnology, including unpredictable impacts and opaque BCIs algorithms, complicate liability allocation. To address these challenges, a classified review system should be developed to trace neural data and identify key points leading to infringements. Laws must clearly define standards for damages and penalties in BCIs-related cases, offering users multiple avenues for seeking justice and compensation.

5.4.4 Ethical Committees and Policies

Protecting informed consent requires adherence to ethical standards. BCIs manufacturers, developers, and clinical trial organizations should establish ethics committees to monitor compliance with ethical standards and policies. These committees would regularly review and update policies based on new ethical considerations (Marchant, Tournas, & Gutierrez, 2020). Appointing ethics officers within these organizations would ensure that the day-to-day operations of BCIs adhere to established ethical norms, promoting greater accountability (Adobor, 2006).

5.5 Guarantees of Equality in BCIs

Advancements in biotechnology are propelling BCIs beyond medical applications into human enhancement, raising ethical concerns about exacerbating social inequalities due to uneven access. Addressing these disparities necessitates comprehensive regulatory and policy interventions.

5.5.1 Government's Role in Ensuring Equality and Fairness

Governments are crucial in ensuring equal access to BCIs and safeguarding against unfair treatment. They should guarantee equal access to BCIs by implementing policies that promote broad availability, such as subsidies or public health programs for economically disadvantaged groups. Additionally, to combat algorithmic discrimination, governments should promote the reasonable disclosure of BCIs algorithms. This would help mitigate the "black box" problem by making algorithms more understandable, thereby reducing potential biases.

5.5.2 Public Policy for Fair Access to BCIs

Establishing robust public policies is crucial for ensuring the equitable and ethical deployment of BCIs. For instance, Spain's 2021 Charter of Digital Rights emphasizes

universal access to digital technologies (The President of the Government of Spain 2021), a principle that should extend to BCIs to mitigate disparities among vulnerable groups. Policies should also enforce non-discriminatory BCI use in employment, education, and healthcare, preventing systemic biases in neurotechnology adoption.

5.5.3 Industry's Responsibility in Reducing Bias

Industry associations and professional societies should work to reduce algorithmic bias in BCIs. By establishing discrimination warning systems, industries can proactively identify and address potential biases in their algorithms. These systems would monitor for discriminatory outcomes and ensure fairness across different demographics, such as race, gender, and socioeconomic status. Additionally, industry associations could cooperate with third-party certification bodies to evaluate BCIs algorithms, granting certifications based on safety and fairness standards.

5.5.4 NGO and Media Oversight for BCIs Accountability

NGOs, think tanks, and journalists could serve as critical watchdogs in BCI ethics, scrutinizing corporate compliance with fairness standards. For example, NGOs could investigate how companies implement algorithms, whether they contribute to social disparities, and how they align with industry standards. Public oversight increases transparency and applies social pressure on companies to prioritize fairness and minimize inequalities in BCIs.

6 CONCLUSION

The rapid evolution of neurotechnology, driven by the big data revolution, has significantly accelerated the development of BCIs. However, this progress raises pressing ethical concerns, particularly in security, privacy, human agency, and social equity. While BCIs present challenges that may seem futuristic, it is imperative for legal scholars to anticipate neurotechnological advancements and proactively propose regulatory solutions (Lawrence, Shapiro, & Fins, 2019). This study conducts a comparative analysis of BCI regulations in the U.S., EU, and China, revealing that existing frameworks are ill-equipped to mitigate emerging risks. A comprehensive, multi-stakeholder regulatory approach is essential, integrating government oversight, industry self-regulation, independent agencies, civil society engagement, and international cooperation. By prioritizing proactive governance, this research aims to foster interdisciplinary discourse and global collaboration, ensuring the ethical and sustainable development of BCIs.

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