Brain-Computer Interfaces In The Medical Field: Legal And Ethical Considerations Surrounding The Global Protection Of Human Rights

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Abstract: *This paper explores the ethical and legal implications of brain-computer interfaces, which uniquely connect the human brain to external devices and have the potential to revolutionise the medical field. As BCI technologies advance rapidly, significant ethical concerns have surfaced, particularly regarding regulation and the protection of human rights. The research underscores the urgent need for a coherent global regulatory framework that can effectively address these challenges, emphasising the importance of robust human rights protections in the adoption of such frameworks. The paper employs a multidisciplinary approach that combines technical, policy, and legal analyses to redefine core human rights concepts, such as freedom of thought, right to privacy, integrity, and identity, within the context of BCI use. The study aims to shed light on the fragmented global legal landscape surrounding BCIs and advocate for a unified legal response that safeguards users' rights in an increasingly digital world.*
Keywords: *Artificial Intelligence, Brain-Computer Interfaces, Human Rights, International Governance, Neurorights.*

INTRODUCTION

In recent decades, technological progress has led to the emergence of new frontiers in areas that were previously the exclusive domain of science fiction. Among the most promising and, at the same time, controversial innovations are brain-computer interfaces, devices capable of recording and decoding, or even influencing, the human neural activity, by connecting the brain with external electronic systems, such as computers, prostheses or other digital devices. To date, they represent one of the most advanced frontiers of biomedical technology, as they have the potential to radically revolutionise the fields of medicine and neuroengineering, introducing extraordinary possibilities for improving the cognitive and physical health of human beings.

At the present time, a considerable number of companies across the globe are engaged in the development and testing of their own brain-computer interfaces, with the objective of making them available for sale. Companies including Neuralink, Synchron, Neurable, Emotiv, Kernel, NextMind, and others, are at the vanguard of the development of brain-computer interfaces. Their objective is to engineer revolutionary devices with potential applications extending from medical to consumer neurodevices. Despite having been operational for several years, these companies have only recently become the focus of an intense media scrutiny. This was particularly evident at the beginning of 2024, when Elon Musk made a public announcement regarding the first human implantation of his company Neuralink's Telepathy chip. The potential of this specific implant is to treat serious medical conditions, including paralysis, blindness and neurodegenerative diseases, thereby paving the way for pioneering medical therapies. While there are other companies engaged in similar neurotechnological developments, Neuralink has attracted significant attention for a number of reasons, including the leading-edge advancement of its technologies and the involvement of its founder, a prominent figure in the global technology industry. His public statements, which were often visionary and provocative, contributed to a widespread discussion of the project and thus also of the broader research field. From that moment on, it became clear to the world how such technologies could revolutionise the way humans interact with technology.

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Simultaneously, the concept of implanting microchips in the human brain gave rise to significant ethical debates and concerns. In this regard, it is essential to acknowledge that the aforementioned competitive landscape of businesses operates within a domain that, while not entirely devoid of regulation, lacks explicit provisions or considerations tailored to the unique challenges and requirements associated with neurotechnologies, including brain-computer interfaces. The global regulatory framework remains fragmented, with disparate standards of protection across countries and notable legal ambiguities. Indeed, despite the growing economic and media interest in such technologies, their advancement and integration are occurring within a fragmented global legal landscape, exposing the worldwide user base to significant hazards, particularly in the realms of privacy and security. Such regulatory misalignment is currently fostering competition among manufacturers, who are often prioritising the speed of development over ethical considerations. In the absence of cohesive regulatory guidance, companies are inclined to launch products that have not undergone sufficient testing or to engage in aggressive commercial practices that neglect the long-term implications of brain-computer interfaces, especially regarding users' fundamental rights. It therefore appears clear that a unified global approach to the regulation of BCIs is essential to mitigate risks and protect the user base, ensuring that technological advancements do not outpace the necessary legal and ethical considerations.

The objective of this paper is to examine the ethical and legal implications of brain-computer interfaces, with a specific focus on the safeguarding of rights and principles as enshrined in contemporary international human rights instruments.

This research employs a multidisciplinary approach, with a particular emphasis on the technical, policy, and legal aspects. The modes of inquiry employed are reflected in the three main sections that structure this work.

The initial section presents a technical analysis of brain-computer interfaces, based on a systematic review of scientific literature, including academic articles, research publications, and technical reports. The section presents an analysis of the principal medical applications, thereby delineating the scope of this research, which excludes brain-computer interfaces employed outside the medical field, such as commercial neurodevices designed to facilitate cognitive enhancement for non-medical purposes or to enable broader forms of interaction with computing systems.

The second section of this paper employs a qualitative and comparative analysis of the international policy landscape, with the objective of evaluating the manner in which disparate international organisations are addressing the necessity for a specific and ethically-oriented regulation of brain-computer interfaces.

The third section employs a legal methodology to investigate the influence of brain-computer interfaces on the protection of human rights, with a particular emphasis on the concepts of privacy, autonomy, identity and physical and mental integrity. It examines the applicability of international regulatory instruments, particularly human rights conventions, to BCIs. The section identifies the need of an updated legal framework and proposes prospective models for the protection of relevant interests. Furthermore, it reexamines and redefines concepts such as freedom of thought, privacy, integrity and identity, and considers the potential for the so-called 'neurorights', such as that of cognitive liberty, to be universally recognised.

SECTION I: BRAIN-COMPUTER INTERFACES

1. Definition of neurotechnology and brain-computer interface

The academic literature presents a diverse array of perspectives on the definition of brain-computer interfaces. However, in order to gain an accurate understanding of the nature of such technology, it is first necessary to establish a clear definition of the broader field of neurotechnology, which can actually be promptly retrieved inside the 'Recommendation on Responsible Innovation in Neurotechnology', adopted by the OECD Council on December 11, 2019. According to this document, neurotechnologies are "devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons"[2]. Interestingly, the current spectrum of neurotechnologies encompasses various mechanisms, including those of electronic, optical, magnetic, acoustical, and chemical nature[3], which facilitate an enhanced comprehension of neural processes while permitting researchers' interaction with the human nervous system for a multitude of scopes envisaged by the medical domain.

Notably, the most relevant achievement for the purposes of this field of study has been the development of the so-called brain-computer interfaces (hereinafter 'BCIs'), also known as neural interfaces or brain-machine interfaces. The term was first introduced in 1973 by Jacques J. Vidal. In his paper entitled 'Toward Direct Brain-Computer Communication', Vidal initially defined BCIs as "utilising the brain signals in a man-computer dialogue"[4] and "as a means of control over external processes such as computers or prosthetic devices"[5]. Today BCIs can be essentially defined as computer-based systems that allow users to carry out desired actions while circumventing the body's traditional efferent pathways, such as peripheral nerves and muscles[6]. Indeed, by directly measuring and interpreting brain signals, BCIs enable a bidirectional communication between the nervous system and information and communication technology (ICT) devices, which paves the way for monitoring the brain, exerting a direct control over an external device via the brain, as well as influencing neural activity by means of electrical stimulation of specific regions[7].

2. Current applications in the medical field

BCIs were born to be applied in the medical field. Indeed, their advent is frequently attributed to the pioneering work of Dr. Grey Walter in 1964. During this period, Dr. Walter conducted an unprecedented experiment in which he implanted electrodes into the motor areas of a patient's brain. He connected the electrodes to a slide projector and demonstrated that the patient could advance the slides without physical movement only by utilising the amplified signals from the implanted electrodes in the motor cortex. This is considered the first instance of controlling an external device through brain activity alone[8]. Subsequently, the advancement of this technology in the medical field has been striking. To this day, BCI research continues to offer significant benefits to patients who utilise it, thereby completely revolutionising their lives. The applications of this technology in the medical field are manifold and diverse, given that BCIs are employed for purposes of prevention, diagnosis, treatment, rehabilitation and management of diseases.

Firstly, BCI has the potential to be utilised as a preventative measure. One such example is a prospective treatment for refractory epilepsy, which employs a BCI to automatically detect seizures and trigger stimulation to abort them[9]. Consequently, the integration of BCIs into wearable devices

[2] Organization for Economic Co-operation and Development, "Recommendation of the Council on Responsible Innovation in Neurotechnology", OECD/LEGAL/0457 (Dec. 11, 2019). https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457 Accessed: 24.01.2025.

[3] Rafael Yuste, Tomás de la Quadra-Salcedo, and Miguel García Fernández, "Neuro-Rights and New Charts of Digital Rights: A Dialogue Beyond the Limits of the Law", in *Indiana Journal of Global Legal Studies* 30, no. 1, 2023, p. 21.

[4] Jacques J. Vidal, "Toward Direct Brain-Computer Communication", in *Annual review of biophysics and bioengineering*, vol. 2, 1973, pp. 157-158

[5] Ibid., p. 163.

[6] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", in *15 U. St. Thomas J.L. & Pub. Pol'y*, 2021, p. 329.

[7] Alžběta Solarczyk Krausová, "Legal aspects of brain-computer interfaces", in *Masaryk University Journal of Law and Technology* 8, 2014, p. 201.

[8] Alžběta Solarczyk Krausová, "Legal aspects of brain-computer interfaces", p. 200.

[9] Vladimir Maksimenko et al., "Brain-computer interface for the epileptic seizures prediction and prevention", in *2020 8th International Winter Conference on Brain-Computer Interface (BCI)*, Gangwon, Korea (South), 2020, p. 1.

has facilitated continuous ambulatory monitoring, enabling individuals to engage in their daily activities while the electrical activity associated with seizures is persistently observed[10].

The use of BCIs for diagnostic purposes is becoming increasingly present across various medical fields as well, as their capacity to analyse brain signals in real-time offers a distinctive advantage in the identification and diagnosis of neurological conditions. One notable example is the integration of scalp EEG within BCI technology, which is transforming the diagnosis of brain tumours[11].

With regard to the treatment and restoration of bodily functions, the applications of BCI are of the utmost diversity. Indeed, as will be discussed later on, BCIs may facilitate the restoration of sensory functions, potentially enabling individuals with sensory defects or injuries to regain their vision, hearing, tactile perception, and mobility[12]. Moreover, BCIs may play a role also in the restoration of autonomic functions like bladder and bowel control, sexual function, and the regulation of heart rate and blood pressure[13].

Furthermore, BCI has facilitated the management and, potentially, the treatment of neurodegenerative diseases such as Dementia, Alzheimer's disease and Parkinson's disease[14].

Additionally, the technology facilitates the management of neurological and psychiatric disorders, including cognitive and mood disorders, through the precise modulation of brain activity[15]. This is exemplified by the effective utilisation of BCIs to train individuals to regulate their cerebral signals, thereby alleviating symptoms of depression or Attention-Deficit Hyperactivity Disorder (ADHD) through neurofeedback[16]. Furthermore, novel forms of precision neurotherapy have been devised, whereby neural circuits can be selectively targeted, modulated or even reprogrammed[17].

One of the most pressing objective for clinical BCI research at this time is the development of solutions for individuals diagnosed with Locked-in Syndrome (LiS) and advanced Amyotrophic Lateral Sclerosis (ALS)[18]. As both conditions result in the complete loss of voluntary muscle movement while preserving sensory and cognitive functions, BCIs provide a means of communication and task performance that would otherwise be impossible for these individuals[19]. In this regard, the provision of BCI-based access to computers and virtual keyboards is actually able to facilitate an enhanced communication[20]. In addition, it is now possible also to synthesise speech effectively and to decipher even the earliest attempts at handwriting[21]. Indeed, recent advances in deep neural networks and latent diffusion models have demonstrated the capacity to decode a range

[10] Wireko Andrew Awuah et al, "Bridging Minds and Machines: The Recent Advances of Brain-Computer Interfaces in Neurological and Neurosurgical Applications", p. 142.
[11] Ibid.
[12] Rafael Yuste, "Advocating for neurodata privacy and neurotechnology regulation", in *Nature Protocols* 18, 2023, p. 2870.
[13] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 334.
[14] Wireko Andrew Awuah et al, "Bridging Minds and Machines: The Recent Advances of Brain-Computer Interfaces in Neurological and Neurosurgical Applications", p. 140.
[15] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 334.
[16] Elisabeth Hildt, "Brain-Computer Interaction and Medical Access to the Brain: Individual, Social and Ethical Implications", in *Studies in Ethics, Law, and Technology* 4, no. 3, 2010, p. 5.
[17] Rafael Yuste, "Advocating for neurodata privacy and neurotechnology regulation", p. 2870.
[18] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 333.
[19] Anastasia Greenberg, "Inside the Mind's Eye: An International Perspective on Data Privacy Law in the Age of Brain Machine Interfaces", p. 89.
[20] Elisabeth Hildt, "Brain-Computer Interaction and Medical Access to the Brain: Individual, Social and Ethical Implications", p. 5.
[21] Rafael Yuste, "Advocating for neurodata privacy and neurotechnology regulation", p. 2870.

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of cognitive processes, including also speech perception, semantic representation of images and silent reading[22].

A final, but by no means least, application of BCI in the field of rehabilitation and assistance is the control of prostheses. Indeed, BCIs offer a potential avenue for individuals with severe motor impairments to regain lost motor functions by directly controlling neuroprostheses or other mobility-assisting devices, such as powered wheelchairs, hand orthoses, robotic arms, or powered exoskeletons[23]. Leaving aside impairments that have a purely motor nature, another prevalent type of BCI neuroprosthesis that may be recalled is the cochlear implant, a diminutive electronic apparatus that stimulates the cochlear nerve, thereby enabling patients afflicted with hearing loss to finally discern sounds[24]. Similarly, also a new type of visual prosthesis capable of stimulating neurons in the visual cortex has recently been developed[25].

In conclusion, the centrality of the BCI issue and the importance of discussing it in depth are self-evident when considering the myriad of applications in the medical field. However, the integration of these technologies into medical practices requires not only technological advances, but also profound ethical and legal reflections.

SECTION II: THE CALL FOR A CONCRETE GLOBAL REGULATORY ACTION

As of the present date, national legal frameworks have far proven underdeveloped for the effective regulation of BCIs. Indeed, such technologies are generally legislated as medical products within domestic legal systems and the lack of a more specific regulation on the matter leaves significant issues unaddressed, including the potential for the misuse of such devices and the necessity for transparent and accountable practices in the handling of sensitive neurological information. These deficiencies clearly impede the complete protection of individual rights. Notably, only a limited number of countries such as some U.S. States, Chile, Brazil, the UK, Spain and Colombia have enacted specific legislation aimed at safeguarding individuals' rights from the issues arising from advancements in neurotechnology or have amended their personal data protection legislation to explicitly encompass neurodata. However, these disparate and piecemeal national initiatives are still insufficient to confront the full range of current and prospective challenges posed by BCIs[26].

Given the complexity and global scope of these concerns, it is manifest that more comprehensive and coordinated international regulatory structures are needed to ensure effective protection of rights and responsible governance of BCIs. As science becomes increasingly globalised, addressing new challenges requires a coherent and effective collective response[27]. Technological advancements now transcend national boundaries and impact societies worldwide. In order to effectively address many interconnected issues, including ethical considerations, data privacy, regulatory standards and human rights protections, it is thus essential to adopt a collaborative international approach. Such cooperation could guarantee the harmonisation of regulations and

[22] Ibid.
[23] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 333-334.
[24] Marta Sosa Navarro and Salvador Dura-Bernal, "Human Rights Systems of Protection from Neurotechnologies that Alter Brain Activity", p. 908.
[25] Ibid., p. 909.
[26] Milena Costas Trascasas, "Assessing the human rights impact of neurotechnology: towards the recognition of 'neurorights'", Research proposal presented at the Human Rights Council, Advisory Committee, 28th session, A/HRC/AC/28/2 (Aug. 2022). https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisory committee/session28/2022-08-09/AC28-Human-rights-impact-of-neurotechnology.docx Accessed: 24.01.2025.
[27] State University of New York, Downstate Health Sciences University, UNESCO, University of Milan-Bicocca (Italy), *The Risks and Challenges of Neurotechnologies for Human Rights* (UNESCO Publishing, 2023), p. 30.

policies, fostering innovation while safeguarding against potential risks and ensuring equitable benefits for all populations.

As a matter of fact, without a unified worldwide strategy, fragmented national efforts would inevitably fall short in managing the complexities of modern scientific progress. The challenges are manifold. Foremost among them is the potential for individual countries to undertake the regulation of neurotechnologies without conducting a thorough and comprehensive assessment of the associated implications. This approach could lead governments to focus legislation solely on concerns relevant to their own specific socio-economic and political contexts, while neglecting or failing to adequately address issues that are significant to other cultures, political systems, or economies[28]. Another critical challenge lies in the capacity of transnational actors, such as private technology developers, to circumvent existing human rights norms. Indeed, the conventional international legal framework imposes direct legal obligations on states, frequently excluding non-state actors from its formal scope. Human rights law generally obliges states to protect individuals from violations by non-state actors, rather than holding the actors themselves accountable. This lacuna in governance is especially problematic in the context of rapidly advancing neurotechnologies, where private companies play a central role in innovation and deployment[29]. Further exacerbating these challenges is the decline in multilateral lawmaking, driven by geopolitical tensions and political reluctance among states to regulate large corporations. This decline provides transnational firms with greater freedom to engage in practices such as forum shopping, strategically selecting jurisdictions with minimal regulatory oversight to advance their interests[30].

In light of the aforementioned concerns, numerous international actors have explicitly called for a stance to be taken by states and other international and supranational entities. Indeed, from the perspective of the international governance, numerous international organisations are already playing a crucial role in addressing the need for clarification, while urging member states to guarantee specific protection in their legislation against new emerging forms of fundamental rights violations[31].

The Organisation for Economic Co-operation and Development (OECD) was the first international organisation to take action in this field. Notably, in 2019 it published the 'Recommendation of the Council on Responsible Innovation in Neurotechnology', which is considered to be the very first internationally-recognised standard in the field of neurotechnology governance, serving as a reference point for governments and innovators to navigate the ethical, legal, and societal challenges associated with the emerging neurotechnologies in the medical field. The document places peculiar emphasis on nine principles. For the topics that will be subsequently covered in this paper, the following are of particular importance: the promotion of responsible innovation in healthcare, the prioritisation of safety assessment, the creation of oversight and advisory bodies, the elimination of discrimination, the safeguarding of personal brain data and the anticipation and monitoring of potential unintended use and/or misuse.

Following the publication of this foundational document, the topic of neurotechnology regulation was immediately addressed in Europe as well. In this context, it is pertinent to cite the 2020 Resolution 2344 of the Parliamentary Assembly of the Council of Europe, entitled 'The

[28] Karen Herrera-Ferrá et al, "Contextual and Cultural Perspectives on Neurorights: Reflections Toward an International Consensus", in *AJOB neuroscience*, vol. 14, 4, 2023, p. 360.
[29] Walter Johnson, Lucille Tournas and Reina Magistro Nadler, "Implementing Neurorights: Legal and Regulatory Considerations", in *Neuroethics* 18, 5, 2025, p. 8.
[30] Ibid., p. 9.
[31] State University of New York, Downstate Health Sciences University, UNESCO, University of Milan-Bicocca (Italy), *The Risks and Challenges of Neurotechnologies for Human Rights*, p. 26.

brain-computer interface: new rights or new threats to fundamental freedoms?'[32]. This document actually represents the prime instance in which BCIs are specifically treated as the focal point of an official political declaration. Peculiar is that the Assembly specifically proposes the establishment of new human rights, under the nomenclature of 'neurorights', urging Member States to adopt comprehensive legal and ethical frameworks as well in order to integrate them. The ethical principles highlighted in the present document are consistent with those set forth in the preceding OECD document. Subsequently, as part of its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025), the Council of Europe published also series of fundamental reports, the most significant of which is the one named 'Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field'[33], written by Professor Marcello Ienca. The latter is of particular importance for the purposes of this research, as it is the first document to address extensively the issue of human rights in relation to the use of BCI in the medical field. Indeed, the text provides an exhaustive examination of the proposal of four principal neurorights (namely, cognitive liberty, mental privacy, mental integrity and psychological continuity) and of the academic discourse surrounding their acknowledgement. Given the significance of this subject matter, this paper will offer a comprehensive investigation of it, particularly in Section III.

With regard to the European Union, while it has already in place a fragmented yet relatively comprehensive framework for regulating neurotechnologies within the medical field, encompassing instruments such as the Medical Device Regulation (MDR)[34], the General Data Protection Regulation (GDPR)[35], and the Artificial Intelligence Act (AI Act)[36], there has been a notable lack of explicit public political statements addressing the potential risks to fundamental rights posed by BCIs. Despite the European Union's significant funding of neurotechnologies through its Horizon 2020 and Horizon Europe programmes, which have driven advancements in various neuroscientific fields, the only document explicitly addressing the need for human rights protection in this legal domain is the 'León Declaration on European Neurotechnology: A Human-Centric and Rights-Oriented Approach'[37]. However, this declaration is notably brief and lacks detailed guidance. It was signed by the Ministers for Telecommunications and Digitalisation, who committed themselves to promoting the development of neurotechnologies in a way that is "human-centred and

[32] Council of Europe, Parliamentary Assemby, "The brain-computer interface: new rights or new threats to fundamental freedoms?", Resolution 2344 (Oct. 22, 2020). https://pace.coe.int/en/files/28810/html Accessed: 24.01.2025.

[33] Marcello Ienca, "Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field", Report commissioned by the Committee on Bioethics (DH-BIO) of the Council of Europe (Oct. 2021). https://www.researchgate.net/publication/356412675_COMMON_HUMAN_RIGHTS_CHALLENGES_RAISED_BY_DIFFERENT_APPLICATIONS_OF_NEUROTECHNOLOGIES_IN_THE_BIOMEDICAL_FIELD Accessed: 24.01.2025.

[34] European Union, "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC", Official Journal of the European Union, L 117 (Apr. 5, 2017). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745 Accessed: 24.01.2025.

[35] European Union, "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with regard to the Processing of Personal Data and on the Free Movement of such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation)", Official Journal of the European Union, L 119 (Apr. 27, 2016). https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32016R0679 Accessed: 24.01.2025.

[36] European Union, "Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)", Official Journal of the European Union, L series (Jun. 13, 2024). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689 Accessed: 24.01.2025.

[37] Spanish Presidency of the Council of the European Union, "León Declaration on European Neurotechnology: A Human Centric and Rights-Oriented Approach", (Oct. 24, 2023). https://spanish-presidency.consilium.europa.eu/en/news/leon-declaracion-european-neurotechnology-human-rights/ Accessed: 24.01.2025.

rights-oriented". According to the declaration, the European Commission, in collaboration with the recently established European Centre for Algorithmic Transparency, should facilitate high-level expert discussions with a view to evaluating the extent to which current regulatory and policy frameworks, including forthcoming legislative proposals, safeguard individual and collective rights in the context of neurotechnologies. Nevertheless, it is evident that the political discourse remains at an early, embryonic stage of development.

In the Americas, the Inter-American Juridical Committee on Neuroscience also sought to address the topic as early as 2021 by issuing the 'Declaration on Neuroscience, Neurotechnologies and Human Rights: New Legal Challenges for the Americas'[38]. Its content was furthermore developed inside the subsequent 2023 declaration, entitled 'Inter-American Declaration of Principles Regarding Neuroscience, Neurotechnologies and Human Rights'[39], which stresses the respect for human dignity, privacy, and autonomy, while emphasising the need to safeguard mental integrity, ensure informed consent, and promote equal access to neurotechnological benefits, urging states to establish effective protection mechanisms, especially for vulnerable groups.

A robust and impactful contribution to the global discourse on neurotechnology has actually been proffered by the United Nations Educational, Scientific, and Cultural Organization (UNESCO). Indeed, from an international governance perspective, UNESCO was the first intergovernmental organisation to advocate Member States to incorporate strong protections against emerging violations of fundamental rights into their legislation[40]. In this regard, it is crucial to acknowledge the seminal contribution of the UNESCO International Bioethics Committee. From the legal point of view, the 2021 report, named 'Ethical Issues Of Neurotechnology'[41] addresses the need for "a new set of neuro-specific human rights", namely those referring to the integrity and autonomy of the mind, the continuity of the individual's identity and psychological state, the right to privacy, the accessibility and the pursuit of social justice. Furthermore, it is evident that UNESCO is willing to develop the first international normative instrument to address the pertinent issue. Indeed, as a decision of UNESCO's General Conference at its 42nd session, the Director-General constituted an Ad Hoc Expert Group (AHEG) with the objective of preparing the draft text of a recommendation, which is going to be finalised during the 43rd session, in November 2025. As for today, the draft was distributed to member states in September 2024, with the objective of enabling them to provide comments and observations in preparation for the intergovernmental meeting scheduled for May 2025. If analysed, the 'First Draft of a Recommendation On The Ethics Of Neurotechnology'[42] places particular emphasis on a number of key ethical principles, including human dignity, individual agency, mental privacy, cognitive liberty, equitable access and harm prevention. Furthermore, it proposes specific cybersecurity measures to identify vulnerabilities. In this regard, ethical data

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[38] Inter-American Juridical Committee, "Declaration of the Inter-American Juridical Committee on Neuroscience, Neurotechnologies and Human Rights: New Legal Challenges for the Americas", OCJI/DEC. 01 (XCIX-0/21) (Aug. 11, 2021). http://www.oas.org/en/sla/iajc/docs/CJI-DEC_01_XCIX-O-21_ENG.pdf Accessed: 24.01.2025.

[39] Inter-American Juridical Committee "Inter-American Declaration of Principles Regarding Neuroscience, Neurotechnologies and Human Rights", CJI/RES. 281 (CII-O/23) corr.1 (Mar. 9, 2023). https://www.oas.org/en/sla/iajc/docs/CJI-RES_281_CII-O-23_corr1_ENG.pdf Accessed: 24.01.2025.

[40] State University of New York, Downstate Health Sciences University, UNESCO, University of Milan-Bicocca (Italy), *The Risks and Challenges of Neurotechnologies for Human Rights*, p. 27.

[41] United Nations Educational, Scientific and Cultural Organization, International Bioethics Committee, "Ethical Issues Of Neurotechnology", Report (Dec. 2021). https://doi.org/10.54678/QNKB6229 Accessed: 24.01.2025.

[42] United Nations Educational, Scientific and Cultural Organization, Ad Hoc Expert Group, "Outcome document of the first meeting of the AHEG: first draft of a Recommendation on the Ethics of Neurotechnology (first version)", SHS/BIO/AHEG-Neuro/2024/1.REV (May 2024). https://unesdoc.unesco.org/ark:/48223/pf0000389768?posInSet=1&queryId=cfc56e24-7a88-4b19-90e7-63bcfc4e556b Accessed: 24.01.2025.

processing guidelines for neural and cognitive biometric data are included, with a detailed and authoritative focus on data protection.

Building on this, it must also be acknowledged that, from a political standpoint, the initial stance taken by the United Nations on the issue has been of notable importance as well. In marked contrast to the approach adopted by the Council of Europe, the United Nations did not undertake the responsibility of establishing novel human rights specifically designed to safeguard the mind from the encroachment of BCIs or their misuse. Instead, inside the 2021 Secretary General's Report 'Our Common Agenda'[43], it adopted a relatively conservative approach, asserting that "updating or clarifying our application of human rights frameworks and standards" would suffice as a means of ensuring adequate protection. Nevertheless, this stance was slightly revised following the invitation from the United Nations Human Rights Council Advisory Committee to the drafting group to assess the "need and opportunity of recognising an additional set of rights, in particular neurorights"[44]. Subsequently, on the basis of the aforementioned report, Resolution 51/3 on 'Neurotechnology and human rights' was adopted by the Human Rights Council on 6 October 2022[45], which called upon the Advisory Committee to prepare a comprehensive study "on the impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights", with particular attention to the formulation of recommendations. Furthermore, it requested the UN High Commissioner for Human Rights to highly consider the impact of neurotechnology on human rights and fundamental freedoms within its mandate. To date, the most recent session of the Human Rights Council Advisory Committee on this topic was held in December 2024. The Committee acknowledged the final Report produced by the drafting group, which was officially presented to the Human Rights Council at its 57th session in September-October 2024. The paper, named 'Impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights'[46], "provides action-oriented recommendations on how these issues can be addressed within the Council, its special procedures and its subsidiary bodies in a coherent, holistic, inclusive manner". The draft document requests in particular the Advisory Committee to develop a set of very specific guiding principles regarding the application of the human rights framework to neurotechnology, which will be submitted to the Human Rights Council in September 2025, at its 60th session. Moreover, in December 2024, the Advisory Committee also resolved to submit a research proposal, entitled 'Elaboration of Guiding Principles on the Application of the Human Rights Framework to Neurotechnology', to the Human Rights Council for consideration and approval. Consequently, developments in this regard remain ongoing.

In conclusion, it appears evident that politics significantly influences the adoption and effectiveness of rights protection systems, since political leaders and international organisations shape legal and regulatory frameworks based on their priorities, ideologies, and power dynamics. Up until this point, neurotechnology has clearly not been a significant focus for legal systems.

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[43] United Nations, Secretary General, "Our Common Agenda", Report (Sep. 2021). https://doi.org/10.18356/9789210010122 Accessed: 24.01.2025.

[44] Milena Costas Trascasas, "Assessing the human rights impact of neurotechnology: towards the recognition of 'neurorights'", Research proposal presented at the Human Rights Council, Advisory Committee, 28th session, A/HRC/AC/28/2 (Aug. 2022). https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/session28/2022-08-09/AC28-Human-rights-impact-of-neurotechnology.docx Accessed: 24.01.2025.

[45] United Nations, General Assemby, Human Rights Council, Resolution 51/3 on "Neurotechnology and human rights", A/HRC/RES/51/3 (Oct. 6, 2022). https://daccess-ods.un.org/access.nsf/Get?OpenAgent&DS=A/HRC/RES/51/3&Lang=E Accessed: 24.01.2025.

[46] Milena Costas Trascasas, "Impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights", Paper presented at the Human Rights Council, Advisory Committee, 31th session, A/HRC/AC/31/CRP.1 (Feb. 2024). https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/sessions/session31/a-hrc-ac-31-crp-1.docx Accessed: 24.01.2025.

Despite this, in just a few years, neurorights have transitioned from a theoretical concept to a significant topic of discussion within international political arenas. Today there is a clear and remarkable convergence of opinion among international organisations, including groups of concerned academics, scientists, engineers and technologists, professional societies and national governmental bodies, on the necessity for common points to be established in order to ensure that human rights and general BCIs standards are met[47].

With respect to this discussion, it is essential to recall that the ethical guidelines, declarations, resolutions, and recommendations presented in the preceding pages do not possess legal authority. Rather, they fall under the category of soft law and serve as supplementary tools to existing legislative frameworks[48]. It should be acknowledged, however, that this is not a completely negative point. Indeed, the diverse applications of BCIs in the future will require a combination of soft and hard governance tools to be addressed: soft governance has the potential to promote ethical responsibility and flexibility among diverse actors, including states and private entities. In contrast, hard governance provides clear, authoritative safeguards. Together, these complementary approaches can balance innovation with accountability, supporting the responsible and ethically grounded development of this kind of technologies.

SECTION III: THE HUMAN RIGHTS IMPACT OF BRAIN-COMPUTER INTERFACES

1. Reconceptualising existing interpretations or framing new human rights?

As can be grasped from the preceding Section II, in comparison with other fields of research, neurotechnology is still in its infancy in terms of subject-related human rights considerations. Nevertheless, as can be observed in the policy statements of the major international organisations, today's primary objective of the international community, even prior to the formulation of comprehensive regulations governing the myriad implications and facets of BCIs in the medical domain, is the actual assurance of a robust and efficacious framework for the protection of individuals' rights. However, it must be highlighted that the academic debate is characterised by a significant degree of divergence in this respect: while certain legal scholars and organisations advocate a transformation in the interpretation of rights currently enshrined in international frameworks of protection of human rights, conversely, other groups and entities emphasise the pressing necessity to recognise novel human rights with the objective of safeguarding the cognitive sphere in a more targeted and effective manner[49].

As previously indicated, the United Nations is among the proponents of the approach that aims to revise the existing international instruments for the protection of human rights. Proponents of this approach generally maintain that the current legal frameworks are sufficiently robust and that enhanced protection of brain data and cognitive integrity can be achieved through an expanded interpretation of existing provisions. This view is reinforced by the broad consensus and widespread acceptance these instruments already hold among state parties.

The second proposed solution envisages instead the improvement of the existing corpus of human rights through the establishment of new rights designed to safeguard brain data and the collective integrity of the human mind. This nascent category of human rights would introduce a new, fundamental level of protection, which is manifestly lacking in the existing frameworks[50].

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[47] Rafael Yuste, "Advocating for neurodata privacy and neurotechnology regulation", p. 2870.
[48] Ibid., p. 2871.
[49] Marcello Ienca, "Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field", p. 66.
[50] Marcello Ienca, "Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field", p. 7.

Indeed, it can be argued that these are rights that, at the time of their initial conceptualisation, were not explicitly acknowledged within any human rights treaty nor otherwise recognised as rights in the legal context[51], but that, nevertheless, offer needed insights into unanswered questions about the conceptual and practical application of neurosciences and of more specific neurotechnological developments such as BCIs. This novel set of human rights for the brain has actually been identified within the relevant academic literature under the designation of 'neurorights'. The term was initially put forth by Marcello Ienca and Roberto Adorno in April 2017. Subsequent years have witnessed a refinement of the definition, whereby neurorights are understood as "the ethical, legal, social, or natural principles of freedom or entitlement related to a person's cerebral and mental domain; that is, the fundamental normative rules for the protection and preservation of the human brain and mind"[52]. From that moment on, the term was met with considerable approval within the academic community, as it efficaciously addressed what was perceived to be a pressing gap in the legal conceptual framework. Indeed, an analysis of contemporary discourse reveals a growing tendency in general comments on international treaties and UN reports to reference technological advances, which can be interpreted as an indication of a potential shift in discourse towards the recognition of neurorights as well[53]. Indeed, given that these rights are not currently in force and therefore do not yet exist in any official sense, it falls upon the states to formally recognise them. However, the process of recognition at the international level is not straightforward and, above all, not univocal. In the first instance, neurorights could either be incorporated into existing protocols or instruments, or else they could be introduced by way of new and topic-specific multilateral instruments. Alternatively, as a second possibility, they could be incorporated into soft law instruments, which frequently become the foundation for customary international law and later treaty adoption. A third potential outcome is that they may evolve to become established customary norms. In such an instance, the application of both the elements of state practice and 'opinio iuris' would be necessary, thereby raising the bar in terms of the requisite conditions. Ultimately, neurorights may also be acknowledged indirectly through a shift in case law by adjudication bodies[54].

In light of the aforementioned points, it can be reasonably posited that the acknowledgement of neurorights may prove a valuable instrument, as the subsequent incorporation of these instruments into national constitutions would afford individuals recourse to domestic court enforcement mechanisms, thereby guaranteeing the efficacy of the right[55]. Furthermore, the recognition of these issues could be instrumental also as an advocacy tool, directing greater attention towards the matter, thus encouraging legislative action on the part of the states[56], as it has been the case with the famous 2021 Chilean reforms, which resulted in the amendment of the constitution, particularly of Article 19, which now explicitly provides for the protection of the right to mental integrity and the neuroprotection of brain activity and its data[57]. Since that seminal event, the concept of neurorights

[51] Nora Hertz, "Neurorights – Do we Need New Human Rights? A Reconsideration of the Right to Freedom of Thought", p. 2.

[52] Marcello Ienca, "On Neurorights", in *Frontiers in human neuroscience*, vol. 15 701258, 2021, p. 1.

[53] Jared Genser, Stephanie Herrmann and Rafael Yuste, "International Human Rights Protection Gaps in the Age of Neurotechnology", p. 6.

[54] Nora Hertz, "Neurorights – Do we Need New Human Rights? A Reconsideration of the Right to Freedom of Thought", p. 9.

[55] Marta Sosa Navarro and Salvador Dura-Bernal, "Human Rights Systems of Protection from Neurotechnologies That Alter Brain Activity", p. 922.

[56] Nora Hertz, "Neurorights – Do we Need New Human Rights? A Reconsideration of the Right to Freedom of Thought", p. 11.

[57] Marcello Ienca, "Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field", p. 65.

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has become the subject of growing debate, with other states also demonstrating their willingness to embrace an approach that aligns with the Chilean perspective.

Nevertheless, it is crucial to acknowledge that the recognition of new rights is not without significant risks, the most pressing of which is the potential dilution of existing rights. This concern, often described as “rights inflation,” arises from the tendency to label all morally desirable claims as human rights. If unchecked, this phenomenon could undermine the credibility and coherence of the human rights framework, fostering skepticism toward its legitimacy and effectiveness.

In conclusion, it is not possible to recognise any claim as a human right. It is, nevertheless, still possible to employ these claims as a means of expanding the interpretation of existing rights. This is exemplified by proposals such as mental integrity, mental privacy and psychological continuity. Indeed, while these concepts may not be recognised as human rights in a standalone sense, they may still be used to update and adapt existing rights in light of the risks posed by BCIs.

2. The neuroright to cognitive liberty

To date, only one conceptualisation of neurorights merits particular recognition for its analytical sophistication, namely that put forth by the legal scholars Jan Christoph Bublitz and Nita A. Farahany[58]. Both authors contend that the introduction of a single additional human right is both necessary and sufficient: that of the right to cognitive liberty.

The right to cognitive liberty actually represents a contemporary but autonomous evolution of the traditional aforementioned concept of freedom of thought. In particular, this updated term is a separate acknowledgement of the current and growing capacity to monitor and manipulate cognitive functions[59]. Indeed, this concept specifically guarantees individuals “the right to alter one's mental states with the help of neurotools as well as to refuse to do so”[60]. The notion thus encompasses both a positive and a negative dimension[61]. On the one hand, it emphasises the individual's autonomy over their mental life, empowering them to make decisions regarding their own cognitive and emotional well-being. On the other hand, it safeguards mental capacities from unwarranted influence by protecting individuals against external attempts to alter their thoughts, emotions, or mental processes without their consent. This protection would ensure that one's mental processes remain free from manipulation or coercion by others, whether through direct intervention with neurotechnological tools or even through more subtle means of influence.

In order to gain an understanding of the reasons why, in contrast with other notions, cognitive liberty must be acknowledged as a new neuroright, it is necessary to highlight three key factors. Firstly, cognitive liberty is an inherent attribute of all human beings, aligning with the definition of human rights as inalienable fundamental rights to which a person is entitled simply by virtue of being human[62]. Secondly, it may be further posited that the right to regulate one's consciousness and electrochemical thought processes represents also the indispensable foundation for nearly every other freedom, thereby making it a constituent element of human rights[63]. Indeed, since they have a direct impact on an individual's capacity to think, reason, and make autonomous decisions, it is evident that consciousness and thought processes are fundamental to human agency, self-determination, and moral judgement. In the absence of control over one's own mind, the capacity to make autonomous decisions, including those pertaining to freedom of speech, political

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[58] Ibid., 4.

[59] Nadine Liv, “Neurolaw: Brain-Computer Interfaces”, p. 350.

[60] Jan Christoph Bublitz, “My Mind Is Mine!? Cognitive Liberty as a Legal Concept”, in Hildt E, Franke AG, eds. “Cognitive Enhancement. An Interdisciplinary Perspective”, in *Springer*, 2013, pp. 233–64.

[61] Nadine Liv, “Neurolaw: Brain-Computer Interfaces”, p. 350.

[62] Marcello Ienca and Roberto Andorno, “Towards new human rights in the age of neuroscience and neurotechnology”, p. 11.

[63] Wrye Sententia, “Neuroethical considerations: cognitive liberty and converging technologies for improving human cognition”, in *Annals of the New York Academy of Sciences*, vol. 1013, 2004, p. 227.

participation, religious expression, and personal privacy, would be significantly undermined. Furthermore, it is through conscious thought that individuals maintain a sense of identity, continuity, and selfhood, all of which are essential to the integrity of all other human rights. Consequently, as it is the neurocognitive foundation for all other liberties, it can be lastly asserted that cognitive liberty cannot be merely subsumed under existing rights and support for this assertion is provided by the fact that it lacks the potential for rights inflation[64].

However, for the analytical purposes of this research, it is crucial to note that, in the future, the concept of cognitive liberty, which represents the fullest and most all-encompassing power over one's own mind, will require balancing with the necessity for medical treatment. Achieving this balance firstly necessitates the safeguarding of the right to reject or consent to treatment, whilst acknowledging that the refusal of essential interventions could result in harm. This interplay gives rise to a series of profound ethical questions concerning informed consent, coercion, and the prioritisation of mental autonomy over public health objectives. It is therefore vital that these competing imperatives are resolved in order to ensure that future governance frameworks respect both cognitive rights and the imperatives of medical necessity and proportionality.

3. The twofold protection of the mind

The academic discourse also frequently addresses the examination of the concepts of mental integrity, mental privacy and psychological continuity. Although these notions cannot be considered as neurorights in a standalone capacity, they can be conceived as being closely interconnected and, in particular, encompassed by the neuroright to cognitive liberty. Indeed, cognitive liberty, as the foundation of all other freedoms, is essential for the protection of mental privacy, mental integrity, and psychological continuity. In its positive sense, it parallels the relationship between freedom of thought and rights to privacy, integrity, and identity. Therefore, just as freedom of thought underpins these rights, cognitive liberty is the basis for safeguarding an individual's mental sphere, protecting against unwanted interference, and ensuring the continuity of personal identity[65].

It is thus imperative that these concepts be discussed further, as they are fundamental to ensuring comprehensive protection of the mental domain. Indeed, the brain can be regarded as the ultimate repository of both informational privacy and human identity, given that it encompasses a vast array of unexecuted behaviours, inner monologues and other actions that are not manifest in the external world and are highly distinctive of the individual in question. The utilisation of BCI technology may, however, result in the inadverted disclosure of these elements, thereby rendering them susceptible to many risks.

In view of the aforementioned considerations, it is imperative to establish a dual-layered framework for the protection of the mind. Firstly, it is crucial to ensure 'ex-ante' safeguards, which focus on proactive measures to protect mental privacy at the earliest stages, even before data are captured, transmitted, or processed by BCIs. These protections aim to prevent the unauthorised collection or misuse of neural data at its origin. In addition, the establishment of 'ex-post' safeguards is of equal importance. These are intended to provide a second line of defence after the data have been processed or utilised, and are designed to shield individuals from potential external intrusions, such as unauthorised access to neural data, and to guard against the manipulation of cognitive or brain functions. The dual approach of proactively preventing risks and reactively mitigating harms ensures a comprehensive framework that aligns with the ethical and legal challenges posed by the development and application of BCIs.

[64] Marcello Ienca and Roberto Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", p. 11.

[65] Marcello Ienca and Roberto Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", p. 24.

Accordingly, in order to compose a research that is both comprehensive and exhaustive, the concepts of mental privacy, mental integrity and psychological continuity will be addressed in the following pages.

3.1 Mental privacy: the 'ex-ante' protection of brain data

In the contemporary digital age, the right to privacy is widely regarded as an indispensable human right, enshrined in foundational instruments such as in Article 12 of the 'Universal Declaration of Human Rights' (UDHR) [66], Article 17 of the International Covenant on Civil and Political Rights' (ICCPR)[67], Article 8 of the 'European Convention on Human Rights' (ECHR)[68], and Article 7 of the 'Charter of Fundamental Rights of the European Union' (CFREU)[69]. In essence, it affords individuals the capacity to determine the extent to which their personal information may be disseminated to others. It is therefore possible to posit that privacy may be conceived not only as a right, but also as an ability[70].

The concept of mental privacy, by extension, stipulates that the content of brain activity, both conscious and unconscious, should not be decoded without the consent of the individual in question[71]. This particular interpretation is based on the premise that the nature of brain data is distinct from that of other forms of personal data. Indeed, brain data are characterised by an intimate nature, representing a first-person perspective on one's inner personhood, thus embodying unique moral relevance. Furthermore, brain activity is directly related to cognitive or affective states, such as emotions, allowing insight into the individuals' perception of the world around them[72]. Therefore, from a philosophical perspective, brain 'reading' represents a profound challenge to an individual's sense of self, as BCIs may be capable of detecting brain states that may be even beyond the subject's conscious awareness. Nevertheless, no efficacious measures have yet been identified to protect mental privacy.

In the context of BCI usage, data, specifically referring to processed brain signal recordings, can be considered a central, cross-cutting infrastructural component of the working of such technology[73]. This is because they are essential to the very functioning of machine learning algorithms, whose effectiveness increases in proportion to the amount of data they process. Interestingly, this characteristic gives rise to a specific privacy-related phenomenon known as the 'privacy paradox': as the demand for data increases to improve the functionality of BCIs, individuals are confronted with the dilemma of trading their mental privacy for the convenience of advanced digital tools or the advancement of medical research. This is particularly evident in Article 7 of the CFREU, which stipulates that the right to privacy is not absolute, as it must be weighed against other

66 United Nations General Assembly, "Universal Declaration of Human Rights", 217 A (III) (Dec. 1948). https://www.un.org/sites/un2.un.org/files/2021/03/udhr.pdf Accessed: 24.01.2025.

67 United Nations General Assembly, "International Covenant on Civil and Political Rights", United Nations, Treaty Series, vol. 999 (Dec. 1966). https://www.ohchr.org/sites/default/files/ccpr.pdf Accessed: 24.01.2025.

68 Council of Europe, "European Convention for the Protection of Human Rights and Fundamental Freedoms", as amended by Protocols Nos. 11 and 14, supplemented by Protocols Nos. 1, 4, 6, 7, 12, 13 and 16 (Nov. 4, 1950). https://70.coe.int/pdf/convention_eng.pdf Accessed: 24.01.2025.

69 European Union, "Charter of Fundamental Rights of the European Union", 2012/C 326/02 (Oct. 26, 2012). https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12012P/TXT Accessed: 24.01.2025.

70 Marcello Ienca, "Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field", p. 29.

71 Rafael Yuste, Tomás de la Quadra-Salcedo, and Miguel García Fernández, "Neuro-Rights and New Charts of Digital Rights: A Dialogue Beyond the Limits of the Law", p. 23.

72 Anita S. Jwa and Nicole Martinez-Martin, "Rationales and Approaches to Protecting Brain Data: a Scoping Review", in *Neuroethics* 17, 2, 2024, p. 8.

73 Stephen Rainey, "Neurorights as Hohfeldian Privileges", in *Neuroethics* 16, 9, 2023, p. 10.

rights, such as those enshrined inside Article 13, which guarantees academic freedom and the freedom to conduct scientific research[74].

Returning to matters of a more technical nature, although the BCI technology itself requires only specific data types to carry out the intended final action, during the initial signal acquisition phase, the entirety of the brain's activity is recorded. This characteristic of the functioning of BCIs clearly shows that their fundamental operation inevitably entails an infringement of mental privacy, as it is not possible for the individual to select by default the specific data types that will be collected. This issue therefore raises significant questions about the ability of individuals to throughly control access to their personal data. To illustrate this point, it is possible to consider a concrete example pertaining to a specific regulatory framework, namely that of the European Union. Indeed, the General Data Protection Regulation (GDPR), particularly in Article 5, stipulates that data are only to be collected for specific purposes and that data outside that precise domain are not to be collected and processed at all. Although no explicit legal reference has been made thus far, it seems probable that, in the future, this rule will not be completely applicable to BCIs. This is because such legal limitation would result in the creation of interfaces with reduced functionality, which would in turn cause problems for their users.

With regard to the processing of cerebral information, instead, in accordance with the prevailing European Union legislation, brain data are considered to fall within the category of health data and are therefore classified as 'sensitive' personal data. The same also happens in other legislations, such as in the U.S. under the federal Health Insurance Portability and Accountability Act (HIPAA)[75]. In the EU GDPR, health data are subject to many strict prohibitions with regard to their processing. Despite this, the processing of data disclosing "racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation" may be permitted, provided that the interested party has been duly informed and has consented to such processing (Article 9 GDPR). In this regard, it can be argued that since BCIs operate through algorithms, the many prohibitions set forth in Article 9 would render the processing of numerous datasets impractical. Therefore, it is evident that the legislation will require a comprehensive revision in order to prevent users from providing total consent to processing solely for the purpose of ensuring the proper and ideal functioning of the BCI devices.

A further technical challenge that must be acknowledged is the potential for re-identification of data, which arises from the recording of information derived from brain activity. Especially in the medical context, the protection of recorded data can be ensured through the process of anonymisation. Indeed, the advent of the open science movement in neuroscience has led to the establishment of a multitude of global data-sharing platforms. Notable repositories in the USA include the International Neuroimaging Data-Sharing Initiative, OpenNeuro, the Human Connectome Project, and the Alzheimer's Disease Neuroimaging Initiative. These have been primarily funded by U.S. federal agencies, including the National Institutes of Health and the BRAIN Initiative. In the European Union, notable repositories include EBRAINS, which was established by the Human Brain Project, and the UK Biobank[76]. The aforementioned databases have been designed in such a way as to permit a high degree of anonymisation of the health data stored within them.

[74] Anastasia Greenberg, "Inside the Mind's Eye: An International Perspective on Data Privacy Law in the Age of Brain Machine Interfaces", p. 98.

[75] U.S. Congress, "Health Insurance Portability and Accountability Act of 1996", Public Law 104 – 191 (Aug 20, 1996). https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf Accessed: 24.01.2025.

[76] Anita S. Jwa and Russell A. Poldrack, "Addressing privacy risk in neuroscience data: from data protection to harm prevention", in *Journal of law and the biosciences* vol. 9,2 lsac025, 2022, p. 4.

However, given the intimate nature of brain data, the more complex and rich they are, the easier it is to re-identify them[77]. Indeed, the risk is that, due to their intrinsic detailed biometric information, it would feasible to distinguish and trace back the identity of individuals, hampering the whole system of protection[78]. The analysis of brain data may thus facilitate the identification of the subjects' current health status and potentially enable the estimation of the prospective risk of developing neuropsychiatric disorders[79]. Hence, it can be argued that a genuine 'inception problem' emerges, insofar as there will be a need not only to safeguard the information itself, but also the source of that information, given their inherent interconnection[80].

For all the aforementioned reasons it becomes evident that an assessment of both the probability and the severity of harm resulting from potential infringements on privacy ought to be conducted in the future by legislators when evaluating the privacy risks associated with the different applications of BCIs[81]. In this regard, the recent legislative action taken by the state of Colorado on April 17, 2024 is worthy of particular mention. Indeed, the Colorado House and Senate passed Bill No. 24-1058[82] to safeguard the privacy of individuals' biological and neural data as private property, following the precedent set by the 2021 Chilean neuroprotection bill. A further number of comparable legislative initiatives are presently under consideration only in Mexico, Brazil, Costa Rica, Colombia, Argentina and Uruguay, although it is anticipated that the number of countries enacting similar measures will expand over the forthcoming years.

3.2 Mental integrity and psychological continuity: the 'ex-post' protection from brain hacking and manipulation

It bears repeating that BCIs have the potential to be used for the commission of extremely harmful crimes. In this context, the term 'neurocrimes' is actually a more accurate designation, encompassing offenses perpetrated against individuals or groups of individuals with the specific intent to cause direct or indirect physical and mental harm, as well as reputational and property damage, by accessing or manipulating neural information through the use of neural devices[83]. A peculiar characteristic that must be noted in this regard is that neurocrime doesn't always require direct access to the brain. Instead, these criminal activities are more likely to happen by indirectly affecting the brain. This could involve tampering with, altering, or disrupting the devices that interact with or process brain functions[84]. Such actions may indeed be exemplified by the hacking of BCIs, the tampering with of neuroprosthetics, the theft of neurodata, the manipulation of neurostimulation devices, or the subtle influencing of cognitive processes without consent. Essentially, these crimes target the technology that connects to the brain, rather than the brain itself, potentially leading to unintended consequences on cognitive processes or brain activity. The concept of 'neurosecurity'

[77] Anastasia Greenberg, "Inside the Mind's Eye: An International Perspective on Data Privacy Law in the Age of Brain Machine Interfaces", p. 101.
[78] Marcello Ienca, "Common Human-Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Field", p. 32.
[79] Anita S. Jwa and Russell A. Poldrack, "Addressing privacy risk in neuroscience data: from data protection to harm prevention", p. 5.
[80] Marcello Ienca and Roberto Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", p. 14.
[81] Anita S. Jwa and Russell A. Poldrack, "Addressing privacy risk in neuroscience data: from data protection to harm prevention", p. 3.
[82] General Assembly of the State of Colorado, " Protect Privacy of Biological Data Concerning protecting the privacy of individuals' biological data, and, in connection therewith, protecting the privacy of neural data and expanding the scope of the 'Colorado Privacy Act' accordingly", House Bill 24-1058 (Apr. 17, 2024). https://leg.colorado.gov/sites/default/files/2024a_1058_signed.pdf Accessed: 24.01.2025.
[83] Marcello Ienca and Pim Haselager, "Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity", p. 119.
[84] Ibid.

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has therefore emerged as the framework for protecting these neural devices from malicious attacks, ensuring the safety and privacy of users' brain data[85].

In considering the principal forms of neurocriminality, two distinct categories emerge: malicious brain hacking and manipulation. Indeed, the integration of BCI devices into daily life introduces both the risk of unauthorised access and of manipulation of neural information, analogously to the hacking of computer systems in the context of computer crimes. In order to protect neural devices, akin to hacking in computer crimes, it is thus necessary to implement stringent safeguards. These safeguards must ensure the confidentiality, integrity and availability of the data stored on the device: confidentiality ensures that private brain data remain secure from intruders, integrity protects the device from being tampered with, and availability guarantees that authorised users can always access the device[86]. In this regard, it is notable that invasive BCIs have proven significantly more vulnerable to intrusion and manipulation, given their higher spatial resolution[87].

With regard specifically to the potential for manipulation, this may be either direct or indirect: while indirect concerns relate to more obliquely implemented techniques such as neuromarketing, direct manipulation is particularly relevant for the purposes of this discourse. This involves the possibility of directly modulating neural activities, thereby altering the subject's behaviour, cognition and affective states through the BCI[88]. Hackers may for instance alter the stimuli presented to the user, thereby potentially disclosing private information. It is noteworthy that the aforementioned scenario bears similarity to the domain of spyware; however, in this case, the hackers in question extract brain signals directly. Measurement manipulation, on the other hand, entails the alteration of the BCI during the data processing, with the objective of disrupting its functions or taking control of the device. The objective of decoding and classifying manipulation, instead, is specifically to generate unintended outputs by introducing noise, interfering with machine learning, or overriding signals, which could result in the replacement of user control. Lastly, feedback manipulation may target the user's perception at the conclusion of each cycle, potentially inducing specific cognitive states or actions for illicit purposes, such as fraud or identity theft[89].

In this respect, it is crucial to highlight the instrumental role that artificial intelligence may play in facilitating and fostering such practices of hacking and manipulation. Indeed, the utilisation of AI, in addition to streamlining the collection, analysis and interpretation of vast quantities of brain data stored within the memory of BCIs, could also potentially be employed to perform long-lasting manipulations. In particular, the opacity of algorithms, coupled with prolonged access to neural interfaces, may render such practices extremely challenging to detect and neutralise. In this regard, while there is currently no regulatory framework explicitly targeting manipulative practices with specific regard to BCIs, the European Union AI Act offers a potential avenue for safeguarding against these activities in instances where they are conducted through the use of algorithms. In particular, Article 5, which enumerates the so-called 'prohibited AI practices', emphasizes, in point (a), the prohibition of the sale, use, or deployment of AI systems that employ subliminal, manipulative, or deceptive techniques to distort a person's ability to make informed decisions, leading to actions they would not normally take, and causing or likely causing significant harm to individuals or groups. To provide context and elucidate the relevance of this specific article to the

[85] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 339.
[86] Ibid.
[87] Elisabeth Hildt, "Brain-Computer Interaction and Medical Access to the Brain: Individual, Social and Ethical Implications", p. 8.
[88] Anita S. Jwa and Nicole Martinez-Martin, "Rationales and Approaches to Protecting Brain Data: a Scoping Review", p. 10.
[89] Marcello Ienca and Pim Haselager, "Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity", p. 122-124.

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broader discourse of this paper, it is essential to cite the interpretive aid offered by recital number 29. As specified in the latter, the manipulation in question "could be facilitated, for example, by machine-brain interfaces (...) as they allow for a higher degree of control of what stimuli are presented to persons, insofar as they may materially distort their behaviour in a significantly harmful manner". Moreover, it is of particular interest for the purposes of this discussion to consider also a further specification that is proposed within the same recital. Indeed, the text additionally states that "the prohibitions of manipulative and exploitative practices in this Regulation should not affect lawful practices in the context of medical treatment such as psychological treatment of a mental disease or physical rehabilitation, when those practices are carried out in accordance with the applicable law and medical standards, for example explicit consent of the individuals or their legal representatives", therefore strongly safeguarding the legitimate and medically-justified practices of brain manipulation that are conducted in accordance with the relevant regulations. In contrast, any and all practices falling outside of the aforementioned scope are strictly prohibited.

In light of the all the proposed evidence, it appears reasonable to affirm that neurocrimes possess the tangible potential to endanger not only the physical, but also the psychological sphere, impairing the sense of identity, personhood, and autonomy of the users. By interfering with a person's cognitive processes or brain functions, these actions may undermine fundamental moral values, including autonomy, free will, and self-determination[90]. In other words, they may infringe on a person's right to control their own thoughts and sense of self, which are in particular fundamental elements of two separate yet interrelated concepts: the notion of mental integrity and the idea of psychological continuity.

In terms of mental integrity, the latter can be conceived as a specific reconceptualisation of an older existing right, namely that of physical and mental integrity. This last notion is reflected in Article 3 of the CFREU, Article 17 of the 'Convention on the Rights of Persons with Disabilities' (CRPD)[91] and in Articles 1 and 7 of the 'Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine' (Oviedo Convention)[92]. Interestingly, the drafters of these human rights instruments intentionally acknowledged the body-mind duality inside their provisions, recognising the fact that interventions involving the brain are more profound and invasive than the majority of other bodily procedures. It is for this reason that the articles in question make explicit reference to the concept of mental integrity. In this regard, it is worth noting that this distinction between physical and mental health, which can be traced back to Descartes' philosophy of body-mind dualism, posits the body and mind as distinct and separable entities[93]. It is, however, also important to acknowledge that despite the widespread integration of this dualism into most legal systems, the protections enshrined in the aforementioned articles are only extended systematically to bodies and brains, and not to minds or mental states. Indeed, current legal frameworks are framed in reductionist tones and largely interpret mental integrity as the right to mental health, addressing it primarily from a psychiatric or psychological perspective[94]. However, with the advent of neurotechnologies, it should become imperative for the law to change this understanding. Indeed, as these technologies have the capacity to interface with and potentially alter cognitive processes, the concept of mental integrity must evolve

[90] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 339.

[91] United Nations, General Assembly, "Convention on the Rights of Persons with Disabilities", A/RES/61/106 (Jan. 24, 2007). https://www.ohchr.org/sites/default/files/Ch_IV_15.pdf Accessed: 24.01.2025.

[92] Council of Europe, "Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine", ETS No. 164 (Dec. 1, 1999). https://rm.coe.int/168007cf98 Accessed: 24.01.2025.

[93] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 351.

[94] Ibid.

to address the broader implications of such interventions. In particular, this broadened scope should not only guarantee individuals with cognitive conditions the right to access psychiatric care, but should ensure the protection of all individuals' mental spheres from undue harm[95]. This implies that the expanded framework should encompass the safeguarding of cognitive functions from any form of unauthorised manipulation or interference, even in the absence of a diagnosable mental condition. The aforementioned arguments lead to the conclusion that this conceptualisation could specifically protect everyone's right to safeguard their mental well-being from potential harm[96]. In this regard, it is important to highlight that, in order for an action to be regarded as an harm to an individual's mental integrity, multiple prerequisites must be met: it must be demonstrated that direct access to and manipulation of neural signalling has occurred; furthermore, it must be established that the action was conducted without the subject's informed consent, and it must be shown that the action caused physical and/or psychological harm[97]. In the event that all of the aforementioned elements are present, it can be reasonably asserted that a genuine infringement of the right to mental integrity has occurred. Consequently, it is imperative that specific protections are duly applied.

With regard to the concept of psychological continuity, instead, this particular recognition stems from the fact that BCIs may potentially cause unintentional shifts in mental states that play a key role in shaping personality, namely changes in how a person thinks, feels, and remembers. Such alterations may not only affect specific mental states but could also disrupt the continuity of personality traits and memories that form the core of an individual's identity. Indeed, modifications in brain function resulting from brain stimulation through BCIs have the potential to cause unintended alterations in an individual's fundamental mental states and such modifications may even influence memory. Alterations in memory can consequently alter an individual's perception of themselves, which in turn impacts their identity[98]. It must be noted that the inviolability of the individual's personal identity is today protected by the provisions contained in Article 8 ECHR and Article 22 UDHR, which pertain to the safeguarding of psychological continuity, albeit in disparate ways. Article 8 ECHR, which guarantees the right to private and family life, directly protects psychological continuity by safeguarding individuals from intrusions that could disrupt their sense of self and cognitive stability. Indeed, psychological continuity is closely associated with the concept of private life, as it encompasses an individual's mental and emotional stability, the capacity to maintain a consistent sense of self, and autonomy over personal identity. Such intrusions, which disrupt the individual's sense of self, including unauthorised access to mental states or manipulation of cognitive functions, can be considered violations of the right to private life. Accordingly, this article has been interpreted as protecting personal identity and mental autonomy, which are essential for maintaining a consistent sense of self over time. Conversely, Article 22 UDHR emphasises the right to the free development of personality, which is directly associated with psychological continuity as well. A coherent and uninterrupted sense of self is indeed essential for the development of one's personality. Disruptions to memory or cognitive function, whether through neurotechnological interference or other means, have the potential to impair an individual's capacity to fully develop their personality. Collectively, these two articles offer a supplementary approach to the safeguarding of integrity and identity against prospective neurotechnology-facilitated

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95 Ibid.

96 Marcello Ienca and Roberto Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", p. 18.

97 Ibid.

98 Marcello Ienca and Roberto Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", p. 20.

interventions that entail the illicit alteration of a person's neural computation, resulting in harm to the victim[99].

In consideration of the aforementioned aspects, it becomes evident that the notions of mental integrity and psychological continuity are inextricably intertwined. However, they are distinct in terms of their scope: while the right to mental integrity is primarily concerned with the protection of individuals from direct harm to their mental or neural functions, in contrast, the right to psychological continuity extends beyond this to encompass situations where there may be disruptions to a person's mental state that do not necessarily involve direct harm to the brain or mind. This could entail circumstances wherein an individual's identity, personality, or memory may be influenced, even if their mental integrity remains uncompromised. In essence, the right to psychological continuity addresses broader concerns regarding the maintenance of a stable and coherent sense of self over time, extending beyond the mere prevention of direct mental harm provided by mental integrity.

In conclusion, as these concepts gain increasing importance in the years to come, it will fall to legislators to analyse them in depth and determine whether it is legitimate to access or interfere with a person's neural activity and, if so, under what conditions this may occur.

CONCLUSION

This work showed that while the potential of BCIs is undeniably groundbreaking, their development and application in the medical field raise complex ethical, legal and societal issues regarding the integration of the human brain with artificial systems.

As these technologies rapidly evolve, the need for a robust regulatory framework becomes increasingly pressing. The drawbacks associated with prioritising market expansion over responsible innovation are becoming increasingly evident. The establishment of clear global guidelines is imperative, as they could assist producers by promoting responsible innovation, mitigating legal uncertainties, and ensuring ethical progress. Achieving this objective necessitates a balanced and coordinated global regulatory approach, one which is capable of protecting users whilst also fostering sustainable innovation.

Additionally, it has been possible to highlight that at the heart of the legal debate on BCIs are critical issues such as personal autonomy, privacy, integrity and identity, which can not be underestimated by the international legislators. These technologies, while offering promising medical benefits, expose individuals to concerning vulnerabilities such as the potential for unauthorised access to their neural data and for manipulation. As a consequence, ensuring informed consent and protecting the mental sphere against exploitation are paramount to ethically integrating BCIs into the medical practice.

However, the way forward is still highly debated. Whether rights will be expanded remains uncertain, as existing legal mechanisms, supplemented by emerging regulatory approaches such as soft law instruments, may still offer adequate protection. What is clear, though, is that the emergence of neurorights, once a theoretical concern, has now become central to global policy discussions. Undoubtedly, the potential of BCIs to fundamentally alter human cognition and interaction requires legislation to evolve and expand to address the risks and complexities involved. The emergence of new rights cannot be nipped in the bud by overly conservative tendencies, as failure to act proactively may result in unforeseen threats that undermine individual freedoms and core societal values. Nevertheless, while the exploration of neurorights may constitute an indispensable stage in this process, it is imperative to proceed with circumspection in order to preclude any dilution of the intrinsic value of existing human rights.

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[99] Nadine Liv, "Neurolaw: Brain-Computer Interfaces", p. 351.

In conclusion, it appears clear that only through the establishment of comprehensive safeguards and ethical guidelines it will be possible to ensure that these innovations enhance human potential while safeguarding the core tenets of human rights. As BCIs represent a future filled with both promise and peril, it is incumbent upon us to approach this evolving frontier with a combination of thoughtfulness and caution. It is therefore evident that these considerations are of paramount importance in determining the future trajectory of human existence, which will undoubtedly become inextricably intertwined with the domain of artificial intelligence. However, it is imperative for us to ensure that the fundamental essence of what it means to be human will not be compromised during this process.

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