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Legal Protection of Neurodata: Overcoming the Subtle Threats of Neuromarketing

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Chapter 1: Introduction to Neuroscience and Neurotechnology

1. Definition and scope of neuroscience

1.1 Cognitive neuroscience: definition and areas of study

Cognitive neuroscience is a discipline that seeks to achieve the biological foundations of mental life. It is at the intersection of neuroscience, psychology, and cognitive science, exploring how the structure and function of the brain give rise to perception, memory, language, reasoning, and consciousness. Rather than treating the mind and brain as separate, cognitive neuroscience seeks their integration, offering an explanation of how mental experiences arise from neural activity. The birth and development of this area of study began in the near past: 'over the last 30 years or so, a new field called cognitive neuroscience has emerged that is specifically devoted to understanding these issues'[1] i.e., functions such as perception, language, memory, emotions, and consciousness.

To get an idea of the scope of this field, it is useful to situate it within the broader field of neuroscience. Neuroscience is concerned with the study of the nervous system and the brain; it considers the structures and processes of brain function to explore, understand, and develop how these features inform human behavior. The objective of neuroscience is, in fact, 'to understand how nervous systems function. Many important insights can be gained from a vantage point outside the head'[2]. Historically, this area of research has developed through an interdisciplinarity of researchers from medicine, biology, and psychology, among others, to explore relations between brain and mind.

Understanding how the brain works is, in fact, a very complex activity that neuroscience addresses by following a multi-level strategy termed the reductionist approach[3]. Scientists can comprehend the brain functioning by looking at it from different perspectives: at the cellular and molecular level, through systems and behaviors, and right up to the highest

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[1] Dale Purves and others (eds), *Neuroscience* (6th edn, Oxford University Press 2018) 22.

[2] Mark F Bear and others, *Neuroscience: Exploring the Brain* (3rd edn, Lippincott Williams & Wilkins 2006) 20.

[3] The reductionist approach is a general method in science and philosophy that seeks to explain complex systems by analyzing their simplest parts. It is based on the idea that higher-level phenomena, such as those observed in biology or psychology, can be understood by studying the basic physical or chemical processes that underlie them. This view has influenced many scientific disciplines throughout the 20th century and remains central to how many researchers structure investigation, especially in the natural sciences.

level, the cognitive level. Each level adds another dimension to understanding how the brain determines what we do, what we think, and what we feel.

Cognitive neuroscience has emerged as a distinct field reflecting this knowledge about the brain in terms of levels. Historically, psychology focused on observable behavior, and neuroscience on the biology of the nervous system. Their convergence, enabled by advances in brain imaging and experimental methods, has facilitated a more comprehensive understanding of cognition as a biologically grounded phenomenon. Studies analyzing the complexity of brain function reveal that the human brain, indeed, 'can be understood as a complex system or network, in which mental states emerge from the interaction between multiple physical and functional levels'.[4] This *complex system* then 'gives rise to elaborate molecular, cellular, and neuronal phenomena that together form the physical and biological basis of cognition'[5].

Historically, early efforts at localizing brain function laid the foundation for the field. Discoveries such as Broca's and Wernicke's areas[6] for speech production and speech comprehension demonstrated that specific mental capacities could be localized to specific brain regions. The well-documented case of Phineas Gage[7], where personality was significantly altered after frontal lobe damage, further solidified the link between neural structure and behavior. Yet, cognitive neuroscience as we know it today has been shaped by the development of non-invasive neuroimaging methods and behavioral paradigms that seek to explore the mind. From this perspective, 'one approach to cognitive neuroscience is to design and validate specific behavioral tasks that can be used to assess aspects of human or animal information processing and behavior'[8].

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[4] Danielle S Bassett and Michael S Gazzaniga, 'Understanding Complexity in the Human Brain' (2011) 15 *Trends in Cognitive Sciences* 200.

[5] ibid.

[6] The discoveries of Broca and Wernicke in the 19th century established that specific aspects of language are localized in distinct brain regions. Broca's area, located in the left frontal lobe, is responsible for speech production; damage to this area causes non-fluent aphasia. Wernicke's area, in the posterior part of the left temporal lobe, governs language comprehension; lesions here result in fluent but nonsensical speech, known as Wernicke's aphasia.

[7] The case of Phineas Gage, a 19th-century railroad worker who survived a traumatic brain injury caused by an iron rod that pierced his frontal lobe, provided early evidence that specific brain regions are involved in personality and social behavior. Although Gage retained his motor and linguistic abilities, his personality reportedly changed drastically, highlighting the role of the frontal lobes in emotional regulation and executive function.

[8] Purves and others (n 1), 22.

There is a wide variety of methods used in cognitive neuroscience to investigate brain function. Functional magnetic resonance imaging (fMRI) and positron emission tomography (PET) are methods that allow researchers to track the metabolic and hemodynamic events that occur during mental activity. Electroencephalography (EEG) and magnetoencephalography (MEG) provide precise temporal details about the electrical and magnetic fields of the brain. These tools are generally complemented by lesion studies, which examine changes in behavior that result from focal brain damage. At the core of these research activities is the understanding that ‘neurons are the basic units of the brain"[9] and that "neuronal communication requires both an electrical signal (the action potential) and a chemical signal (the neurotransmitter)[10]’. It is this two-signal process that represents the physiological basis for all of the cognitive processes investigated within the field.

Cognitive neuroscience, then, offers a comprehensive framework for understanding how the brain enables the mind, drawing from diverse levels of analysis, from molecular interactions to systems-level brain activity and behavioral expression. By integrating methodologies from neuroscience, psychology, and cognitive science, it has shed light on the neural basis of complex mental phenomena such as perception, memory, language, and executive function. This integrative approach has not only advanced theoretical models of cognition but also laid essential groundwork for applied fields.

Indeed, as the insights of cognitive neuroscience increasingly move from laboratory settings to real-world applications, a natural progression emerges toward the domain of clinical neuroscience. It is here that the biological understanding of cognition finds its most urgent and tangible application: in the diagnosis, treatment, and prevention of neurological and psychiatric disorders. The transition from investigating how the healthy brain supports thought and behavior to examining how disruptions in the brain function lead to dysfunction marks the next critical step in our exploration, a step where theory meets therapy, and science begins to heal.

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[9] Casey Henley, *Foundations of Neuroscience* (Michigan State University Libraries, East Lansing 2021).
[10] ibid 13.

1.2 Clinical neuroscience and medical applications

Clinical neuroscience today represents an advanced meeting point between basic research and medical practice, an interdisciplinary field that has evolved through centuries to become a mainstay of modern medicine. Its roots lie in the late 19th century, when a new method of investigating the brain began to take shape. A real change of direction has developed in this regard: ‘the application of the formal experimental method required a combination of carefully planned, goal-directed work … Simple clinical observation and deduction were no longer enough.’[11] This shift marked a decisive break from the previously dominant phenomenological approach, which relied heavily on descriptive accounts of symptoms and behaviors. Instead, neuroscience began to adopt a rigorously empirical model based on experimental validation, controlled observation, and quantifiable data, laying the groundwork for a scientific understanding of brain function rooted in reproducibility and precision: ‘the foundations of the related disciplines of clinical neurology and neuroscience were laid down in that era’.[12]

As for today, clinical neuroscience represents one of the most dynamic and fascinating areas of brain research. At the heart of this field is the underlying idea that to truly understand mental and neurological disorders, we must first understand how our nervous system works or stops working.

Clinical neuroscience is distinguished from experimental neuroscience by its close connection to medical practice and direct observation of patients. In fact, ‘clinical research is mainly conducted by physicians (M.D.s). The main medical specialties associated with the human nervous system are neurology, psychiatry, neurosurgery, and neuropathology’[13]. These disciplines work with the goal of understanding and treating disorders of the nervous system through clinical observation and therapeutic intervention. One of the main areas of study in clinical neuroscience concerns the evaluation of the efficacy and safety of new therapeutic approaches, with the goal of improving available treatment tools. A key step forward in this regard has been the development of neurotechnologies, tools that allow us to “see” the brain in action. Techniques such as

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[11] Michael Swash, ‘Henry Head and the Development of Clinical Neuroscience’ (2008) 131 *Brain* 3453.

[12] ibid.

[13] Bear (n 2), 14.

functional magnetic resonance imaging (fMRI) and electroencephalography (EEG) now allow us to map brain activity with an accuracy that only a few decades ago seemed like science fiction. Leading scholars in the field point out that it is now possible to use these technologies not only to study the brain, but also to anticipate the evolution of certain disorders: ‘patterns of fMRI activity can also predict the probability of remission from clinical depression and potentially guide treatment choices’[14].

Another crucial and growing area within clinical neuroscience is the investigation of social and affective functioning. Understanding how individuals engage in social contexts, regulate emotions, and develop moral behavior is not only a theoretical pursuit, but a clinical imperative.

Indeed, deficits in social cognition are central to numerous neurological and psychiatric conditions, including autism spectrum disorder, schizophrenia, and various forms of dementia. As pointed out in recent research, ‘despite the indisputable importance of living in a structured society for human affective and cognitive processes, how the human brain works throughout simple to complex social contexts remains largely elusive’[15]. This insight highlights the need to further explore the neural mechanisms underlying social behavior, from everyday interactions to complex group dynamics. Clinical neuroscience, by integrating methods from social neuroscience, aims to translate these findings into diagnostic and therapeutic advances, shedding light on impairments in empathy, trust, or emotional regulation, and informing targeted interventions. This focus on the social brain expands the scope of clinical practice, bridging biological analysis with the lived reality of patients’ relational worlds.

This growing attention to the social dimension of brain function has also opened the way for new forms of data collection and analysis, which go beyond the observation of isolated neural responses. The complexity of social behavior, shaped by context, experience, and individual variability, demands integrative models capable of capturing patterns across multiple levels of information. It is precisely in response to this need that recent advances in computational neuroscience and digital technologies have begun to offer powerful

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[14] Elissa M Aminoff and others, ‘The Landscape of Cognitive Neuroscience: Challenges, Rewards, and New Perspectives’ in Michael S Gazzaniga (ed), *The Cognitive Neurosciences* (4th edn, MIT Press 2009) 1259.

[15] Lucas R Trambaiolli and others, ‘Brain Imaging Methods in Social and Affective Neuroscience: A Machine Learning Perspective’ in Paulo Sérgio Boggio and others (eds), *Social and Affective Neuroscience of Everyday Human Interaction: From Theory to Methodology* (Springer 2023) 225.

solutions. In this perspective, with the advent of digital technologies and artificial intelligence, neuroscience has been enriched with a new tool for investigation and treatment: big data.

As highlighted in recent literature, ‘big data, characterized by its diverse and up-to-date datasets, plays a pivotal role in uncovering causal pathways and previously unknown correlations’[16], providing new avenues for the understanding of disease dynamics. By integrating genetic, metabolomic, clinical, and environmental data, medicine is now able to build personalized treatments on an individual basis.

Indeed, it has been noted that ‘big data applications are trending in medicine, including neuroscience. They have contributed to improving overall patient care, decision-making, and personalized treatment’[17]. This unique approach makes it possible to identify early biomarkers, predict the evolution of a disease, and build tailored treatment plans, particularly in complex areas such as neurodegenerative diseases, psychiatric disorders, and chronic conditions.

As the scope of neuroscience expands through technological and analytical innovation, it becomes increasingly clear that understanding brain function requires more than biological data alone. The interpretation of complex behaviors, symptoms, and mental states also depends on conceptual frameworks that describe how cognitive processes are organized and disrupted. This convergence has given rise to a deeper integration between clinical neuroscience and cognitive science, laying the foundation for a more precise and structured approach to diagnosing and treating brain disorders.

Within this framework is the growing importance of clinical cognitive neuroscience, an area that aims to structure clinical thinking around well-defined cognitive categories. As pointed out, ‘clinical brain sciences could gain much from closer links to cognitive sciences. Related to this, is the emerging need for consistent cognitive ontologies’[18]. The use of shared ontologies is not only an epistemological need, but a clinical necessity: without a clear and consistent definition of concepts such as attention, consciousness,

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[16] Ousman Bajinka and others, ‘Big Data for Neuroscience in the Context of Predictive, Preventive, and Personalized Medicine’ (2025) 16 *EPMA Journal* 18.

[17] ibid 29.

[18] Graham Pluck and Kris Ariyabuddhiphongs, ‘Clinical Cognitive Sciences’ in Alessandro Aldini (ed), *Software Engineering and Formal Methods: SEFM 2023 Collocated Workshops, CIFMA 2023 and OpenCERT 2023, Revised Selected Papers* (Springer 2024) 138.

memory, or agency, communication among specialists results in fragmentation and the therapeutic approach risks losing effectiveness.

This issue becomes even more pressing when clinicians are confronted with complex symptoms that resist simple classification. As has been emphasized, ‘there is a need for cognitive analyses that focus on the clinical issues. Furthermore, some issues that are important clinically are of only tangential connection to psychology or neuroscience’[19]. In such cases, relying solely on existing cognitive or neuroscientific models may not be sufficient. A more tailored and clinically relevant framework is needed, one that bridges conceptual clarity with practical applicability in diagnosis, treatment planning, and interdisciplinary collaboration.

Overall, the integration of history, technology, cognition, and clinical practice now shapes a dynamic and deeply interdisciplinary field of applied neuroscience. From the investigation of empathy in everyday interactions to the development of personalized computational models and interactive learning systems, clinical neuroscience has become fertile ground for innovation and transformation in medicine. Each tool, whether a foundational methodology, a social interface, or an artificial intelligence algorithm, contributes to a shared goal: improving health and deepening our understanding of human beings in their biological, cognitive, and relational complexity.

However, the true transformative potential of clinical neuroscience lies not only in the observation and analysis of brain processes but in the ability to intervene in them. To do so, it is necessary to go beyond diagnostic tools and integrate advanced therapeutic solutions. And it is in this direction that the next chapter, devoted to neurotechnologies, moves innovative tools that promise to redefine the relationship between mind, brain, and technology, opening new frontiers for the treatment, cognitive enhancement, and prevention of neurological disorders.

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[19] ibid 140.

1.2 Neurotechnology: innovations and future prospects

1.2.1 Invasive and non-invasive devices

Invasive and non-invasive neurotechnologies represent two basic modes of interaction with the nervous system. The former include brain implants such as Deep Brain Stimulation (DBS), which involve physically introducing devices into the brain, the latter, such as electroencephalography (EEG), allows the detection of neural signals without penetrating the cranial barrier. Taking this first definition into account, it should be noted that, ‘the distinction between invasive and non-invasive is increasingly unclear’[20].

At a deeper conceptual level, the boundary between invasive and non-invasive begins to erode when we examine the physiological basis of the signals involved. According to Steyrl et al., although invasive and non-invasive brain-computer interface (BCI) signals appear different in form, ‘the underlying origin of electrical BCI signals is the same’[21]. This directly undermines the notion that these two modalities interact with fundamentally different neural phenomena.

Furthermore, the classification may be the product of siloed scientific communities, each with its terminology and assumptions: ‘the perceived controversy has several causes: … different research communities with a lack in exchange of information and different naming conventions’[22]. This suggests that the invasive/non-invasive dichotomy is sustained not only by technological differences but also by institutional and linguistic inertia. Within this context, the concept of invasiveness becomes increasingly complicated, ‘the terms used in the discussion are arguably conceptually problematic … invasiveness tends to be viewed as purely physical, the concept obscures the potential for significant invasiveness through non-physical means’[23]. For example, non-invasive BCIs may still allow third-party access to mental states or behavioral intentions, thus raising

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[20] Arleen Salles and others, *Towards Inclusive EU Governance of Neurotechnologies* (Centre for Future Generations and the Institute of Neuroethics 2024) https://cfg.eu/towards-inclusive-eu-governance-of-neurotechnologies/ accessed 17 July 2025, 3.

[21] David Steyrl and others, ‘On Similarities and Differences of Invasive and Non-Invasive Electrical Brain Signals in Brain-Computer Interfacing’ (2016) 9(7) *Journal of Biomedical Science and Engineering* 393.

[22] ibid 394.

[23] Salles (n 20), 38.

critical concerns about privacy and mental integrity. Ethical considerations therefore do not map neatly onto the physical structure of the device.

To overcome such ambiguous categorizations, some authors propose adopting a different terminology, rather than speaking of invasiveness in a purely surgical sense, a more functional distinction could be drawn between '"implantable" and "non-implantable"'[24] technologies. This shift would help capture a wider range of cognitive, ethical, and experiential impacts, offering a more nuanced framework for both regulatory and philosophical discourse.

This conceptual critique of the invasive/non-invasive dichotomy gains further relevance when technical innovations give rise to hybrid forms that no longer fit neatly within traditional classifications. For example, the so-called minimally invasive technologies could be defined as a bridge between the two categories: these include methods that 'require direct brain access but that do not penetrate neural tissue'[25], such as electrocorticography (ECoG) grids or endovascular electrodes. In recent years, noninvasive brain stimulation technologies, such as tDCS (transcranial direct current stimulation), have also begun to be increasingly used in home and nonclinical settings, often for cognitive enhancement rather than therapeutic purposes. This trend has grown significantly since 2011, 'when lay individuals began to construct tDCS devices in their homes. Since then, dozens of companies, largely based in the U.S., have marketed ready-to-wear tES devices for brain optimization and cognitive enhancement'[26] fueling a consumer market that offers these devices as tools to improve attention, memory and creativity, even in healthy individuals.

Such technologies are therefore used far beyond the strictly clinical setting, finding their way into educational, sports or work environments, and becoming part of personal self-improvement routines. However, numerous risks are associated with this casual use: 'brain stimulation devices marketed for consumer use are distinct from medical devices because they do not make medical claims and are therefore not necessarily subject to the same level of regulation'[27].This means that while potentially affecting sensitive brain

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[24] ibid.

[25] BJ Edelman and others, 'Non-Invasive Brain-Computer Interfaces: State of the Art and Trends' (2025) 18 *IEEE Reviews in Biomedical Engineering* 27.

[26] Andrea Antal and others, 'Non-Invasive Brain Stimulation and Neuroenhancement' (2022) 7 *Clinical Neurophysiology Practice* 157.

[27] ibid 147.

functions, many of these devices escape the strict controls expected of medical technologies. The increasing prevalence of these devices in extra-clinical settings, coupled with the ease of access and the absence of clear regulatory barriers, poses new and complex regulatory and ethical challenges, so there is certainly an urgent need to establish a consistent and inclusive regulatory framework for home and nontherapeutic neurotechnologies as well.

1.2.2 Brain-computer interfaces (BCI)

Brain-computer interfaces (BCIs) represent one of the most promising innovations in neurotechnology because of their ability to translate neural activity into commands useful for controlling external devices, such as prosthetics, computers, or alternative communication systems. These technologies are particularly useful for people with motor or speech disabilities, but they also have applications in cognitive, educational, and even recreational areas. A BCI system consists of five basic steps: ‘signal acquisition, pre-processing, feature extraction, classification, and control interface’[28]. The classification step involves interpreting the extracted features by assigning them to specific mental states or intended actions, often using machine learning algorithms. While invasive BCIs offer an advantage in terms of resolution and signal quality due to direct contact with neural tissue, noninvasive ones are rapidly evolving and ‘hold exceptional clinical value due to their non-surgical nature, safety, and scalability’[29].

Noninvasive BCIs are becoming increasingly effective thanks to innovations in dry electrodes, deep learning algorithms, and new protocols for decoding motor intention. In particular, they are proving effective in areas such as post-stroke motor rehabilitation, ADHD, autism, and depressive disorders: ‘systems based on electroencephalography (EEG) eliminate implantation risks and are widely applicable [...] showing promise in neurofeedback therapy for depression, attention modulation in ADHD, and social skills training for autism’[30]. At the same time, advances in flexible and biocompatible technologies are revolutionizing the architecture of BCI devices, new materials reduce

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[28] Usman Salahuddin and others, ‘Signal Generation, Acquisition, and Processing in Brain Machine Interfaces: A Unified Review’ (2021) 15 *Frontiers in Neuroscience* 1.

[29] Shugeng Chen and others, ‘Brain–Computer Interfaces in 2023–2024’ (2025) 3 *Brain-X* 2.

[30] ibid.

inflammatory response and improve comfort for chronic applications: ‘flexible biocompatible interfaces that reduce immediate implantation trauma and chronic foreign-body responses, allowing studies to be performed in live animals over extended periods’[31].

Such developments enable the design of more ergonomic, adaptable, and durable BCIs, facilitating their integration into daily life and long-term therapeutic pathways. Another area of expansion is wearable BCIs for everyday applications, in this area, acceptability and usability are crucial factors: ‘these tools combine the features of neuroimaging technologies with the convenience of wearable devices, enabling real-time exploration of brain activity in real-world contexts’[32].

However, challenges remain related to comfort, accuracy in detecting cognitive load, and psychological acceptance by the user. Finally, the debate between invasive and noninvasive BCI is not limited to technical performance, but touches on ethical, social, and legal issues. As BCIs become increasingly integrated with the human body, ‘the traditional distinctions the law makes are being questioned’[33] especially regarding whether harm to a BCI constitutes property damage or personal injury. The authors argue that under certain conditions, BCIs ‘should be regarded as part of the individual rather than property because it can more accurately capture the harm being caused’[34]. This ambiguity underscores the urgent need for updated legal frameworks that recognize the evolving relationship between neurotechnology and personal identity.

1.2.3 Artificial intelligence applied to neurotechnology

Artificial intelligence (AI) is rapidly emerging as one of the most potent forces in the field of neurotechnology, promising to transform the treatment of neurological diseases and improve human cognitive abilities. Today, as examined in the previous section, many of the most advanced applications involve devices such as brain-computer interfaces (BCIs),

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[31] Pancheng Zhu and others, ‘Advanced Flexible Brain–Computer Interfaces and Devices for the Exploration of Neural Dynamics’ (2024) 2 *Brain-X* e70009, 4.

[32] Ilaria Lombardi and others, ‘Usability and Acceptance Analysis of Wearable BCI Devices’ (2025) 15(7) *Applied Sciences* 3512, 1.

[33] Lachlan Robb and Scott Kiel-Chisholm, ‘Person, or Property? Brain–Computer Interface Technology and the Law’ (2024) 49(1) *Alternative Law Journal* 21.

[34] ibid 25.

which, through AI, can decode brain signals to control external devices. One example of such devices is neuroprosthetics, which 'have evolved from simple devices offering limited functionality to sophisticated systems … The integration of AI has been pivotal in this evolution, enhancing the speed and accuracy of signal interpretation and device responsiveness'[35].

AI-powered neuroprosthetics, including brain-computer interfaces (BCIs), are now moving beyond basic functionality, transforming from early research tools into practical solutions for everyday use. Another area of interest about these technologies concerns the use of Virtual Reality (VR) and Augmented Reality (AR) tools[36], which allow even more functional use of artificial intelligence in areas such as neurosurgery or robotics, in fact 'the recent technological advances in AI, VR, AR, and robotics have made it possible for humans and machines to collaborate to improve healthcare delivery'[37].

The relationship between artificial intelligence (AI) and neurotechnology is not only about the clinical aspect, but also extends to the field of entertainment and human enhancement. Applications of AI in neurotechnologies offer new opportunities not only for treating neurological diseases, but also for enhancing the cognitive and sensory abilities of individuals. In addition, the combination of AI with devices such as brain-computer interfaces (BCIs) can enhance the interactive experience in different fields like video games, while neuroenhancement is emerging as a possibility for expanding human potential.

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[35] Mohan Raja Pulicharla and Varsha Premani, 'AI-Powered Neuroprosthetics for Brain–Computer Interfaces (BCIs)' (2024) 12(1) *World Journal of Advanced Engineering Technology and Sciences* 110.

[36] See par. 1.3.3

[37] Kimia Kazemzadeh and others, 'Advances in Artificial Intelligence, Robotics, Augmented and Virtual Reality in Neurosurgery' (2023) *Frontiers in Surgery,* 7.

1.3 Practical applications of neurotechnology

1.3.1 Neurotechnologies in therapeutic contexts

Neurotechnology represents one of the most promising frontiers in modern medicine, offering transformative potential in the diagnosis, treatment, and rehabilitation of neurological disorders. With the rapid evolution of these technologies, significant strides have been made in both the basic and clinical realms of neuroscience, driven by technological advancements that provide increasingly sophisticated tools for interacting with the brain. 'Technological advances in neural interfaces are providing increasingly more powerful "toolkits" of designs, materials, components, and integrated devices for establishing high-fidelity chronic neural interfaces'[38]. These innovations allow for more accurate, long-term interactions with the brain, paving the way for a new era of therapeutic possibilities.

The applications of neurotechnologies are vast, ranging from devices that simply monitor neural activity to those capable of influencing brain function directly. These technologies have the potential to aid in understanding the intricate workings of the brain and offer significant therapeutic benefits. Specifically, they have 'the potential to help neuroscientists gather information that might help uncover some of the secrets of the biology underlying the normal and pathological functioning of the human brain'[39]. This ability to record, monitor, and even modulate brain activity provides crucial insights into neurological disorders, including conditions such as Parkinson's disease, epilepsy, and chronic pain. In turn, this knowledge aids in developing more targeted and effective treatments.

In this regard (as previously examined in chapter 1.2.2), one of the most successful applications of neurotechnology in therapeutic contexts has been the development of Deep Brain Stimulation (DBS). This technique has been revolutionary in managing conditions like Parkinson's disease through neuromodulation. More precisely, 'neuromodulation describes the type of neurotechnology used in deep brain stimulation

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[38] Daryl R Kipke and others, 'Advanced Neurotechnologies for Chronic Neural Interfaces: New Horizons and Clinical Opportunities' (2008) 28 *Journal of Neuroscience* 11830.

[39] Roongroj Bhidayasiri, 'The Grand Challenge at the Frontiers of Neurotechnology and Its Emerging Clinical Applications' (2024) 15 *Frontiers in Neurology* 1314477, 1.

(DBS) for reducing tremors and other symptoms of Parkinson's disease, and in spinal cord stimulation for treating chronic pain'[40]. DBS has shown remarkable success in improving the quality of life for patients by directly stimulating specific areas of the brain, thus alleviating symptoms that are otherwise difficult to treat with traditional methods. Such therapies exemplify how neurotechnologies, particularly those focusing on the brain's electrical activity, can offer significant therapeutic benefits for patients with debilitating conditions. However, the rise of predictive neurotechnologies devices designed to anticipate and manage neurological events such as seizures has brought new ethical challenges. In fact, 'the problem with predictive neural devices, in particular advisory ones, is the risk of seeing one's autonomous choice supplanted by the predictions instead of being supplemented by it'[41].

While these technologies offer significant promise in improving patient outcomes, they also raise critical questions about autonomy. As these devices gain accuracy, there is a growing concern that patients may begin to rely too heavily on the predictions they provide, potentially undermining their own decision-making and agency. The ethical dilemmas surrounding predictive devices underscore the need for careful consideration in their implementation, ensuring that they complement rather than replace personal autonomy. This concern becomes even more pronounced in contexts outside of healthcare, particularly within the criminal justice system.

Recent studies have explored the possibility of using neurotechnologies to predict recidivism in offenders, suggesting that brain activity, specifically in the anterior cingulate cortex (ACC), could help forecast the likelihood of future rearrests. In a study of adult offenders, 'the odds that an offender with relatively low anterior cingulate activity would be rearrested were approximately double that of an offender with high activity in this region, holding constant other observed risk factors'[42]. This finding raises the question of whether predictive neurotechnologies could be used to make decisions about individuals' future behavior in legal contexts. While such tools could provide valuable insights into risk assessment, they also bring forward the potential for over-reliance on

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[40] ibid 2.

[41] Alberto Tacca and Frederic Gilbert, 'Why Won't You Listen To Me? Predictive Neurotechnology and Epistemic Authority' (2023) 16 *Neuroethics* 22.

[42] Eyal Aharoni and others, 'Neuroprediction of Future Rearrest' (2013) 110 *Proceedings of the National Academy of Sciences of the United States of America* 6223.

technological predictions, replacing human judgment with automated processes that may undermine personal freedoms and legal rights.

Moreover, the impact of neurotechnologies on the individual's psychological and emotional state cannot be overlooked. ‘While obvious medical side effects as dizziness, vomiting … are easy to detect and report, changes in the ability of reflection, emotional balance, altruistic behavior, and commitment to relations are much harder to assess’[43]. This highlights an important aspect of the therapeutic use of neurotechnologies: their potential to influence not only physical health but also mental and emotional well-being. The integration of neurotechnologies into a person's life may alter their sense of self, which brings about complex challenges in both clinical and ethical contexts. The effects of these changes, especially in terms of personal identity and autonomy, are often difficult to measure, but they are critical in assessing the overall success and impact of these technologies.

As neurotechnologies continue to advance, we face new questions regarding their broader societal implications. As one study notes, ‘given the critical role considerations of agency, self-perception and personal identity play in assessing the ethical and legal significance of these technologies, our findings reveal a critical gap in the existing literature’[44]. The way these technologies alter or enhance cognitive and physical capabilities challenges existing norms around what it means to be human and raises questions about the ethical boundaries of enhancement. As we embrace these innovations, it is essential to consider not just their clinical efficacy but also their long-term impact on individuals’ lives and their societal roles.

Neurotechnologies hold immense promise in therapeutic contexts, offering solutions to some of the most challenging neurological disorders. However, as these technologies evolve, so too must our understanding of their ethical, psychological, and social implications. The responsible development and deployment of neurotechnologies require a careful balance between their potential to heal and their capacity to transform the very essence of human identity. By addressing both the technological and ethical challenges they present, we can ensure that neurotechnologies, at least within the medical and

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[43] Thomas Stieglitz, ‘Why Neurotechnologies? About the Purposes, Opportunities and Limitations of Neurotechnologies in Clinical Applications’ (2021) 14 *Neuroethics* 7.

[44] Georg Starke and others, ‘Qualitative Studies Involving Users of Clinical Neurotechnology: A Scoping Review’ (2024) 25 *BMC Medical Ethics* 89.

therapeutic context, could serve as a force for good in advancing human health and well-being.

1.3.2 Use of neurotechnology for cognitive enhancement

As discussed in the previous chapter, neurotechnologies were initially developed with medical and therapeutic purposes in mind; over the years, however, their use has expanded well beyond patient care, opening up possibilities for enhancing the cognitive abilities of healthy individuals. Indeed, neurotechnologies are now also being investigated for their potential to modulate and enhance cognitive functions beyond therapeutic contexts. The idea that cognitive functions like memory, attention, problem-solving, and concentration can be optimized, not just for treatment, but also to boost the mind, has given rise to a whole new field of research related to the concept of cognitive enhancement. This shift from treatment to enhancement has sparked a lot of excitement, as neurotechnologies have the potential to push the limits of human cognitive abilities. But as these technologies offer incredible possibilities, they also raise important questions. What does it really mean to improve cognitive abilities? Where do we draw the line between treatment and enhancement? And, perhaps most importantly, what are the risks that come with the widespread use of these technologies for cognitive enhancement?

These concerns take on a similar complexity when enhancement occurs not through devices, but through pharmaceuticals. Drugs originally intended for clinical use, such as stimulants or mood stabilizers, are now commonly used by healthy individuals to boost attention, memory, or mental performance. In these cases, the physician may be asked to authorize a form of enhancement rather than provide care, shifting the professional's role from healer to enabler. This situation challenges the foundational distinction between treatment and optimization, especially when no clear medical condition justifies the intervention. As bioethicists have observed, ‘the boundary between therapeutic-restorative and enhancement of functions and capacities can sometimes be blurred and, in any case, presupposes a prior agreement on what is considered “norma”' and “abnormal”'[45].

Beyond individual autonomy, the widespread use of pharmacological enhancement raises broader social concerns. The normalization of these practices risks devaluing concepts like personal effort, fairness, and social cooperation. As Lucio Romano warns, the increasing reliance on cognitive enhancement drugs may lead to the ‘wearing down of values such as personal effort and of political-social values (loyalty, fairness, social solidarity, equality of opportunity, cooperation, common citizenship, etc.)’[46]. If cognitive success becomes chemically induced, social expectations and definitions of achievement may shift in ways that undermine collective ethical commitments. This makes it crucial for neuroethics to question not only whether enhancement is feasible, but also whether it is socially and morally desirable. The ethical and social questions raised by pharmacological enhancement apply with equal, if not greater, force to neurotechnological interventions. In this context, the challenges are not limited to issues of fairness or autonomy but extend to deeper questions about the nature of cognition itself and the shifting boundaries between mind, body, and technology.

To fully understand the implications of neurotechnologies in cognitive enhancement, it’s helpful to think about the Extended Mind Thesis (EMT), a philosophical theory developed by Clark and Chalmers. The philosophers use the story of Otto, an imaginary character, to explain the theory of the extended mind. Otto is a man who suffers from memory loss and uses a notebook to write down all important information. When he needs to remember something, he consults the notebook. Clark and Chalmers use this example to argue that, if Otto relies on the notebook as part of his cognitive process, the notebook itself can be considered part of his mind. In other words, the mind is not confined to the brain but extends to external tools that support and enhance our cognitive processes.

This perspective challenges traditional views of cognition by redefining the boundaries of mental processes, suggesting that our minds are dynamically distributed across brain, body, and environment in a seamless, integrated system.

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[45] Italian National Committee for Bioethics, *Neuroscienze e potenziamento cognitivo farmacologico: profili bioetici* (opinion, 22 February 2013) https://bioetica.governo.it/media/3485/p106_2013_enhancement-cognitivo_it.pdf (author’s translation).

[46] Lucio Romano, ‘Enhancement cognitivo e nuovo umanesimo digitale’ in Andrea Patroni Griffi (ed), *Bioetica, diritti e intelligenza artificiale* (Mimesis 2023), 142 (author’s translation).

Clark and Chalmers argue that:

> the human organism is linked with an external entity in a two-way interaction, creating a coupled system that can be seen as a cognitive system in its own right. All the components in the system play an active causal role, and they jointly govern behaviour in the same sort of way that cognition usually does. If we remove the external component the system's behavioural competence will drop, just as it would if we removed part of its brain. [47]

In other words, when an individual consistently uses a piece of technology to improve something like memory or concentration, that technology could be considered part of their cognitive process.

This makes the line between the "natural" and the "enhanced" much blurrier. The human mind might not only be defined by its internal processes anymore, but also by the tools and technologies that help enhance those processes. This way of thinking opens a whole new perspective, where the mind is viewed as an extended entity that is interconnected with the world around it; as our cognitive processes become more intertwined with external devices, the concept of the mind as an isolated, self-contained entity becomes increasingly outdated. Instead, the mind may be viewed as a dynamic, extended system that relies on both internal neural processes and external tools to function effectively. While this perspective offers exciting new possibilities for cognitive enhancement, it also brings with it a set of challenges. The more we integrate technology into our cognitive systems, the more we expose ourselves to potential risks, particularly concerning the integrity and privacy of our mental processes.

In this sense, Heersmink explains:

> humans are creatures whose embodied brains are situated in a technological and social ecology of cognitive scaffolding. Such scaffolding enhances human cognition by providing information that is relevant for performing a cognitive task

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[47] Andy Clark and David Chalmers, 'The Extended Mind' (1998) 58 *Analysis* 8.

> or by allowing us to manipulate and process the external information in a way that is difficult to do in our brain. [48]

The broadening of the very concept of cognitive mechanism toward these external scaffolds seems to have ‘some worrisome implications for mental integrity. Intuitively, if the mind extends beyond the brain, then the mind becomes considerably more vulnerable to invasion, and environmental interventions could threaten mental privacy and privileged access’[49].

This raises important ethical questions, as the integration of external devices into our cognitive processes could expose individuals to unforeseen risks, particularly regarding their mental autonomy and privacy. This further complicates the traditional view of the mind as a self-contained entity. As we rely more on neurotechnologies, the boundaries between what is "naturally" part of our cognition and what is technologically augmented become increasingly difficult to define. While in the past, these neurotechnologies were primarily available in clinical or therapeutic settings, in recent years, a growing number of devices have been made available directly to consumers, without needing any kind of medical intervention. These devices are now marketed as tools to improve cognitive functions like memory, focus, and mental clarity. They’re no longer being used just for people with cognitive impairments but also for healthy individuals who want to boost their productivity, improve their learning capacity, or even just achieve a greater sense of mental well-being.

The rise of DTC (Direct-to-consumer) neurotechnologies has made these tools more accessible than ever before, with people now able to purchase them online and use them in the comfort of their own homes. The document *Neurotechnology and Noninvasive Neuromodulation: Case Study for Understanding and Anticipating Emerging Science and Technology*, published by the US National Academy of Medicine, offers an in-depth analysis[50] of the market for direct-to-consumer (DTC) neurotechnologies, focusing in

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[48] Richard Heersmink, ‘Extended Mind and Cognitive Enhancement: Moral Aspects of Cognitive Artifacts’ (2017) 16 *Phenomenology and the Cognitive Sciences* 22.

[49] Tom Buller, ‘Mental Integrity, Neurotechnology, and the Extended Mind Thesis’ (2025) 18 *Neuroethics* 13.

[50] Debra Mathews and others, *Neurotechnology and Noninvasive Neuromodulation: Case Study for Understanding and Anticipating Emerging Science and Technology* (Discussion Paper, National Academy of Medicine 2023) https://nam.edu/neurotechnology-and-noninvasive-neuromodulation/ accessed 18 July 2025.

particular on transcranial direct current stimulation (tDCS) devices. Among the devices listed in the document, there are examples such as LIFTiD neurostimulation, marketed to enhance attention and focus and the PlatoWork brain stimulator, designed to stimulate specific brain areas related to memory, creativity, and focus. Another noteworthy example is the ActivaDose tDCS device, the only device FDA-approved for investigational use, often recommended by physicians and used in clinical trials. The variety of these devices and their commercialization in the absence of clear regulatory standards point to a growing trend toward self-managed cognitive enhancement, while simultaneously raising questions about safety, efficacy, and accessibility. As the document emphasizes, ‘there are significant barriers to governance at the level of the consumer, where private individuals purchase and use DTC products at home, or purchase components and build their own devices’[51]. The case study concluded that, despite the potential of these tools, the lack of clinical oversight and the variability in scientific evidence of their effectiveness highlight the urgent need for the development of a multilayered governance framework to ensure the safe and equitable use of DTC neurotechnologies.

1.3.3 Neurotechnology in virtual and augmented reality

In recent years, the convergence of virtual reality (VR), augmented reality (AR) and neurotechnologies has opened new frontiers in medicine, education and human-computer interaction. The integration of these immersive technologies with neural systems now makes it possible to create tools capable of modulating, enhancing or even rehabilitating cognitive and motor functions, offering personalized and immersive experiences. One of the most promising areas is cognitive rehabilitation. VR, through its ability to create safe and controlled environments, enables ‘immersive, interactive, and adaptable therapeutic experiences’[52] that overcome the limitations of conventional rehabilitation approaches. In particular, it is emphasized that VR improves attention, memory, and problem-solving skills in patients with cognitive impairment. The ability to receive real-time feedback and the interactivity of the virtual environment contribute to increased patient motivation and participation in the rehabilitation process.

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[51] ibid 11.

[52] Atukunda Lucky, ‘Virtual Reality in Cognitive Rehabilitation: Engineering User Experiences’ (2025) 6(1) *Newport International Journal of Current Issues in Arts and Management (NIJCIAM)*. 42.

In addition to medicine, VR and AR are also revolutionizing the fields of education and experiential learning: according to some researchers, 'education is revealed as one of the main domains in which their use is mostly examined due to their potential to offer immersive, personalized, and interactive learning experiences'[53]. This could lead to a more engaging and effective way of teaching, especially in contexts where sensory interaction plays a key role.

Consumer behavior has also been transformed by the introduction of virtual reality, particularly in the context of so-called immersive commerce. Personalized virtual experiences, high sensory quality, and emotional engagement are considered key factors in enhancing the customer experience. It has been observed, for example, that 'VR significantly influences consumer purchase behavior, especially among young hedonic consumers. Factors like cost, convenience, and VR quality impact VR adoption, while personalized entertainment enhances engagement and sales'[54]. The strategic use of virtual reality by global brands such as IKEA[55] or Coca-Cola[56] demonstrates the growing relevance of these technologies for marketing and customer loyalty.

A particularly interesting application is also found in the field of neurosurgical training and anatomical visualization in neuroscience. The three-dimensional spatial complexity of brain structures poses a substantial challenge to learners, and 'VR has gained vast interest as a novel approach to facilitate an immersive, interactive, and efficient learning experience in the study of human anatomy in general and in particular, of neuroanatomy'.[57] In this study, real human brains were used to develop highly detailed 3D models through photogrammetry. These were placed in a custom-built virtual laboratory where participants could 'walk around freely, explore, and manipulate (i.e., lift the models, rotate them for different viewpoints, etc.)'[58]. The results demonstrated that students who engaged in this VR environment 'show a gain in spatial understanding and

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[53] Georgios Lampropoulos, 'Intelligent Virtual Reality and Augmented Reality Technologies: An Overview' (2025) 17(2) *Future Internet* 58.

[54] Suvodip Sen, 'A Systematic Review of Relationship between Virtual Reality and Purchase Behaviour' (2025) 14(3) *International Journal of Latest Technology in Engineering Management and Applied Science* 242.

[55] See https://www.ikea.com/global/en/newsroom/innovation/ikea-launches-ikea-place-a-new-app-that-allows-people-to-virtually-place-furniture-in-their-home-170912/ (accessed 18 July 2025)

[56] See https://www.coca-cola.com/gb/en/media-center/coca-cola-zero-sugar-takeatastenow-campaign (accessed 18 July 2018)

[57] Nadav Aridan, 'Neuroanatomy in Virtual Reality: Development and Pedagogical Evaluation of Photogrammetry-Based 3D Brain Models' (2024) *Anatomical Sciences Education* 240.

[58] ibid.

an increased satisfaction with the learning experience, compared with traditional learning approaches*'*[59].

As mentioned above, the synergy between neurotechnology and virtual/augmented reality represents a major breakthrough in the design of human experiences, rehabilitation processes, and training. The effectiveness of these technologies, however, depends on careful user-centered design, rigorous scientific evaluations, and an interdisciplinary approach that also considers ethical and social implications. In fact, there are 'compelling reasons to speak of VR as a user experience phenomenon rather than a technology alone, where the technological focus shifts from the stability of hardware to designing appealing and effective user experiences'[60].

1.4 Neurodata: definitions and classifications

1.4.1 Definitions: brain data, neurodata, and mental data

In recent years, the accelerated development of neurotechnology and artificial intelligence has made it urgent to clarify how to define and regulate information about the human brain and mind. Three related but distinct terms have gained particular relevance in this context: brain data, mental data and neurodata. Although often used synonymously, each refers to a different level of the information sphere derived from brain and cognitive activity. Understanding these differences is critical to developing an appropriate regulatory framework and protecting people's fundamental rights.

According to the OECD Recommendation on Responsible Innovation in Neurotechnology, "brain data" are 'data relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health, or mental states'[61]. Both anatomical measurements (such as MRI images) and functional measurements (such as EEG signals), obtained through neuroimaging or neuroregistration techniques, fall into this category. Consequently, not

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[59] ibid 246.

[60] Lucky (n 52).

[61] OECD, Recommendation of the Council on Responsible Innovation in Neurotechnology (OECD/LEGAL/0457, 2019) section II ('Personal brain data') https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457.

all brain data contain mental information: for example, data describing brain morphology may be clinically relevant but say nothing about what a person is thinking. Their legal sensitivity therefore depends on their use and context, although because of their uniqueness and potential identifiability, they are often considered sensitive personal data. The concept of neurodata, as defined in the European Data Protection Supervisor's *TechDispatch 2024-1* includes both data collected directly from the brain and nervous system and inferences from them, such as emotional clues or preferences. This definition also includes signals from the peripheral nervous system, collected through invasive or noninvasive devices, and actively or passively collected. The paper points out that 'neurodata can be generally defined as the information gathered from the brain and/or from the nervous system. … we also consider as neurodata inferences based directly on this data such as emotional cues or preferences'[62]. The use of neurodata is becoming increasingly common in non-medical fields such as marketing, education, entertainment and security, but for this very reason it raises significant fundamental rights concerns, particularly the possibility of uniquely identifying people and interfering with their most intimate sphere.

Building on this, both the EDPS and the UK Information Commissioner's Office (ICO)[63] have emphasized the distinctiveness of neurodata in relation to other types of biometric or behavioral data. One key aspect concerns the involuntary nature of neurodata: it is generated subconsciously, often without deliberate intention or awareness on the part of the data subject. As the ICO explains, '*ne*urodata is subconsciously generated and people have no direct control over the specific information which is disclosed'[64], a quality that renders it uniquely sensitive and ethically problematic. This lack of volitional control differentiates neurodata from most other personal data, complicating the traditional model of consent and calling into question how informed or autonomous such consent can truly be.

Furthermore, the normative sensitivity of neurodata is not solely determined by its biological source, but also by the purposes for which it is processed. As the *TechDispatch*

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[62] European Data Protection Supervisor, *TechDispatch 2/2023: Brain-Computer Interfaces* (2024) https://edps.europa.eu/data-protection/our-work/publications/techdispatch/techdispatch-22023-brain-computer-interfaces_en. (accessed 26 July 2025) 4.

[63] Information Commissioner's Office, *Tech Futures: Neurotechnology* (2023) https://ico.org.uk/about-the-ico/what-we-do/tech-futures/neurotechnology/ (accessed 26 July 2025).

[64] ibid 6.

underlines, the same neurophysiological information might be treated differently under the law depending on whether it is used for healthcare, commercial profiling, or behavioral prediction. This purpose-driven approach to legal qualification is essential, particularly in light of practices such as brain fingerprinting[65] or emotional inference[66], which may cross thresholds of intrusiveness that demand heightened protection. The EDPS explicitly warns that such processing 'should only occur for healthcare purposes, accompanied by all data protection conditions and safeguards'[67].

In this sense, neurodata categorization challenges not only how we define personal data, but also how we apply core principles of data protection law. Existing frameworks centered on purpose limitation, data minimization, and accuracy may not be sufficient unless adapted to the epistemological complexity and predictive potential of neural information. Misinterpretations or inaccuracies in neural signal processing can have irreversible consequences on an individual's autonomy, mental health, or social standing. For these reasons, the EDPS and ICO both call for a contextual and proportionate regulatory approach that integrates evolving ethical considerations and is responsive to new forms of risk.

These developments point to a broader ethical horizon, in which the legal qualification of neurodata cannot be separated from emerging discussions on neurorights. As neural information begins to mediate decisions in education, employment, and security, its regulation will increasingly intersect with fundamental questions about identity, agency, and the nature of thought itself.

The concept of mental data further expands the picture. It has been defined as 'any data that can be organized and processed to infer the mental states of a person, including their cognitive, affective, and conative states'[68]. This recognition of this category calls for a rethinking of the traditional scope of rights related to freedom of thought. While historically protections have focused on the external manifestation of thought (its

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[65] Brain fingerprinting is a forensic technique developed by Lawrence Farwell that detects recognition of information through brainwave responses. See https://farwellbrainfingerprinting.com

[66] Emotional inference refers to the process by which neurotechnological systems interpret or predict a person's emotional state based on neural, physiological, or behavioral data, often without explicit self-report. The concept is central to affective computing and was first systematically explored by Rosalind Picard in the mid-1990s. See R W Picard, *Affective Computing* (MIT Press 1997).

[67] EDPS, *TechDispatch 2/2023* (n 62), 16.

[68] Marcello Ienca and Gianclaudio Malgieri, 'Mental Data Protection and the GDPR' (2022) *Journal of Law and the Biosciences* 1.

expression in speech or action) mental data introduce the need to safeguard the *genetic* moment of thought itself. In other words, legal and ethical frameworks must now extend into the forum internum[69], ensuring that the processes by which thoughts, emotions, and intentions are formed remain free from unjustified interference.

However, it should be noted that mental data can be derived from both neural and nonneural sources. They can be inferred from brain signals through neural decoding processes or from behavioral and phenomenal information such as voice recordings, facial expressions, or digital interactions. What characterizes them is their ability to reveal thoughts, emotions, intentions, memories, preferences, and other mental states, even in the absence of overt behavioral expressions; this makes them potentially more sensitive than other types of personal data.

The difference between these three categories is not only terminological but also reflects different levels of complexity and normative implications. Brain data are structural or functional data about the brain; neurodata include the latter but also include processing and inferences related to the nervous system; and finally, mental data represent the broadest and most sensitive category, since they concern mental states themselves, whether inferred from neural signals or behavioral traces. As digital technologies allow more and more information about people's mental states to be inferred, even predictively and in real time, it is urgent that the law properly recognize and protect these new forms of data. Mental data, in particular, challenge traditional distinctions between physical, psychological and informational privacy, and require new safeguards that reflect their exceptionally intimate nature.

1.4.2 Neurodata as personal and sensitive data

In the context of the increasing prevalence of neurotechnology, the concept of neurodata is becoming central to data protection law. The term, as noted in the previous chapter, refers to all information derived directly from the human brain, such as electrical brain

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[69] The term *forum internum* originates in medieval canon law, notably in Gratian's *Decretum* (c 1140), where it distinguished the internal forum of conscience from the *forum externum* of public conduct. This distinction became central in Catholic theology and survives in modern legal discourse to denote the inner domain of thought and belief, which enjoys absolute protection under international human rights law, such as Article 18 of the International Covenant on Civil and Political Rights (ICCPR) and General Comment No 22 of the UN Human Rights Committee.

signals, functional or structural activity of the central nervous system, and the inferences that can be drawn from them.

At the legal level, the first crucial aspect relies on the understanding of whether neurodata is personal data. Article 4(1) of the General Data Protection Regulation (GDPR) defines personal data as 'any information relating to an identified or identifiable natural person'[70]. Neurodata fully meets this criterion, as it can not only be directly linked to an individual, but can even contain some kind of *neural signature*, that is, a description of unique and unrepeatable traits. Data processing in the context of the GDPR encompasses a wide range of operations, going far beyond simple storage or collection: 'data processing has a very broad definition and is likely to include most of the operations that are likely to occur in collecting and storing brain data'[71]. This implies that in most cases, neural data, when collected and processed through automated technologies, fall fully within the material scope of the GDPR, making it necessary to adopt the safeguards provided for personal data.

A second, more complex issue concerns the qualification of neurodata as sensitive data under Article 9 of the GDPR. The latter provides enhanced protection for special categories of personal data[72]. It should be pointed out, however, that 'there is a clear conceptual and normative gap: even though most people would agree that mental data are the most intimate and sensitive information of the data subject, not all mental data are protected under the strict regime of sensitive data'[73].

This observation opens the door to a broader reflection on the nature of sensitive data and the importance of context in determining their level of protection. An important aspect in defining what qualifies as "special categories of personal data" is that their sensitivity is not always intrinsic to the data itself but may emerge depending on the specific context in which the data is processed. This perspective is supported by the EDPB Guidelines 03/2020, which clarify that information may become health data 'because of its usage in

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[70] 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 (General Data Protection Regulation) [2016] OJ L119/1, art 4(1).

[71] Stephen Rainey and others, 'Is the European Data Protection Regulation Sufficient to Deal with Emerging Data Concerns Relating to Neurotechnology?' (2020) *Journal of Law and the Biosciences* 5.

[72] GDPR, art 9(1): 'Processing of personal data revealing 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 shall be prohibited'.

[73] Ienca n (68) 10.

a specific context (such as information regarding a recent trip to or presence in a region affected with COVID-19 processed by a medical professional to make a diagnosis)'[74]. This indicates that data not originally classified as sensitive can acquire that status when interpreted or used within a certain framework, especially in health-related scenarios, where implications for individual privacy can be significant. The example provided by the EDPB reflects a broader understanding under the GDPR, according to which the classification of personal data into a special category is not static, but relational and functional, tied to the purpose and manner of its processing.

This context-dependent understanding of data sensitivity also finds support in the now-repealed Article 17[75] of the Italian Data Protection Code (Legislative Decree no. 196/2003, as amended in 2018). Although the provision is no longer in force, it remains significant from a theoretical standpoint. It established that public entities were allowed to process personal data (even when such data did not explicitly fall under the category of sensitive data) only when expressly authorized by a specific law or regulation and within the limits of their institutional functions. This reflected an awareness that the collection of certain types of personal data, though not inherently sensitive, could still pose significant risks to the data subject, thereby requiring a prior risk assessment and proportionality evaluation. This requirement implicitly acknowledged that the sensitivity of personal data is not determined solely by its intrinsic content, but also by the institutional context and the power asymmetry involved in its processing. In other words, what qualifies as sensitive or potentially invasive may depend as much on who processes the data and for what purpose, as on the nature of the data itself. This view[76] anticipates

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[74] European Data Protection Board, *Guidelines 03/2020 on the Processing of Data Concerning Health for the Purpose of Scientific Research in the Context of the COVID-19 Outbreak* (21 April 2020) https://www.edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_en.pdfaccessed 18 July 2025, 5.

[75] Legislative Decree No 196 of 30 June 2003 (Italian Data Protection Code), art 17 (repealed): '1. The processing of data other than sensitive or judicial data that presents specific risks to the rights and fundamental freedoms, as well as to the dignity of the data subject, due to the nature of the data, the methods of processing, or the effects it may produce, is permitted only with the adoption of safeguards and precautions for the data subject, where required. 2. The safeguards and precautions referred to in paragraph 1 are prescribed by the Data Protection Authority in accordance with the principles set out in this Code, as part of a prior checking procedure before processing begins, which may also concern certain categories of controllers or types of processing, and may be initiated following a request by the controller' (author's translation).

[76] The principle was confirmed by the Italian Data Protection Authority (Garante per la Protezione dei Dati Personali), in its decision no. 87 of 19 May 2020, concerning statistical surveys conducted by the National Institute of Statistics (ISTAT). The Authority underlined the importance of applying enhanced safeguards when processing data related to minors or concerning sensitive social phenomena, even where such data

the more functional and relational conception of data protection later reinforced by the GDPR.

In other words, based on the analysis so far, it is clear that there is a mismatch between the potentially sensitive content of neurodata and the formal categorization provided for in European legislation. This discrepancy depends on the issues connected with the very nature of sensitive data and the importance of context in determining their level of protection.

Although neurodata are not always formally recognized as sensitive data[77], there is a growing body of evidence that suggests that they should be considered as such. This is because of their ability to reveal information that is extremely intimate and difficult for the individual to control. Indeed, the collection and processing of data directly derived from brain activity is not limited to the return of physiological parameters but can provide privileged access to dimensions of psychic identity such as intentions, emotions or cognitive predispositions. In this sense, it has been noted that neurodata represents a unique form of data, which has unprecedented characteristics in comparison to other types of personal information, and for which the current legal system 'may be insufficiently equipped, or constructed'[78]. The uniqueness of neurodata also stems from its predictive capacity: brain recordings obtained through neural interfaces, for example, 'may be used to predict future user behavior, brain states, and other aspects of activity that are relevant to the user's identity'[79].

These characteristics make it clear how their processing can significantly affect the privacy of individuals, to the point of justifying enhanced qualification, even where not formally provided for in current legislation.

On the other hand, some point out that the concept of sensitive data itself is evolving. The increased technological ability to infer mental states from apparently innocuous data dilutes the definition of sensitivity to the point where it becomes inadequate if anchored solely in taxonomy categories. Some authors propose a different solution, namely 'a

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may not, at first glance, fall under special categories pursuant to Article 9 GDPR. This approach reflects a contextual interpretation of data sensitivity, where the purpose, environment, and subjects involved play a crucial role in defining the degree of protection required.

[77] See GDPR, art 9.

[78] Dara Hallinan and others, 'Neurodata and Neuroprivacy: Data Protection Outdated?' (2014) 12(1) *Surveillance & Society* 55.

[79] Rainey, *Is the European Data Protection Regulation Sufficient to Deal with Emerging Data Concerns Relating to Neurotechnology?* (n 70) 3.

hybrid approach where a purpose-based definition plays a greater role in deciding whether data is sensitive, combined with a context-based “backstop” based on reasonable foreseeability’[80]. This means that the sensitivity of a piece of data should be determined not only by its membership of predefined categories, but also by the purpose for which it is processed and the context in which it is processed. For example, if a piece of data is used with the intention of revealing sensitive information, or if it is reasonably foreseeable that this will happen, then it should be considered sensitive. This logic reflects what could be described as the *fil rouge* of data protection law: the centrality of the purpose of processing as a guiding criterion throughout the data lifecycle, clearly affirmed in Opinion 03/2013 of the Article 29 Working Party, which emphasized that ‘personal data must be collected for “specified, explicit and legitimate'” purposes (purpose specification) and not be “further processed in a way incompatible” with those purposes (compatible use)’[81]. This approach is particularly relevant to neurodata, which, while not always falling within the traditional categories of sensitive data, can still reveal intimate and personal information about the individual.

In conclusion, the classification of neurodata as personal data is legally sound and widely supported, while its classification as sensitive data requires an evolutionary interpretation of existing law. Because of its intrusive potential, its biological uniqueness and the possibility of making inferences about the most intimate dimensions of human beings, neurodata should be treated de facto and de jure as a highly sensitive category. There is therefore an urgent need for the European legislator to formally recognise this specificity by adopting measures to ensure a substantial protection of cognitive and mental privacy.

1.4.3 Biometric and genetic neurodata

This section continues the analysis begun in the previous one, which showed how neurodata, understood as data generated by the monitoring of brain activity using neurotechnological technologies, falls, under the General Data Protection Regulation

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[80] Paul Quinn and Gianclaudio Malgieri, ‘The Difficulty of Defining Sensitive Data—The Concept of Sensitive Data in the EU Data Protection Framework’ (2021) 22 *German Law Journal* 1583.

[81] Article 29 Working Party, ‘Opinion 03/2013 on Purpose Limitation’ (2 April 2013, WP 203) https://ec.europa.eu/justice/article29/documentation/opinion_recommendation/files/2013/wp203_en.pdf accessed 9 July 2025.

(GDPR), both within the notion of personal data under Article 4(1) and potentially within that of data belonging to special categories under Article 9. The discussion now focuses on the possibility of equating neurodata, under certain circumstances, with biometric and genetic data, analyzing the normative basis and theoretical and practical implications of such classification.

The GDPR defines biometric data in Art. 4(14), as:

> personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data. [82]

This category, as provided in Article 9[83], enjoys an enhanced protection regime. From this perspective, neurodata can meet these criteria when they are used to identify an individual based on the uniqueness of brain patterns: 'neurodata are representations of an individual's unique brain structure and functioning'[84] to the extent that they are considered 'even more precise than traditional biometric markers, such as genetic data or fingerprints'[85]. The individual uniqueness of brain structure and functioning gives neurodata an identifying capacity beyond that of commonly recognized biometric parameters.

Just as biometric data (such as fingerprints or facial geometry) require technical processing to extract and interpret their identifying features, neurodata must also undergo complex decoding to become meaningful. Raw brain signals alone (e.g., EEG waves) do not reveal personal identity or mental content unless analyzed through specific instruments, such as sophisticated algorithms, capable of correlating those signals with specific individuals or mental states. In both cases, it is the act of processing that transforms raw physiological input into personal, and potentially sensitive, information.

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[82] GDPR, art. 4 (14)

[83] See n 72.

[84] Timo Istace, *Neurodata: Navigating GDPR and AI Act Compliance in the Context of Neurotechnology* (Geneva Academy of International Humanitarian Law and Human Rights, December 2024) https://www.geneva-academy.ch accessed 18 July 2025 3.

[85] ibid.

The link to genetic data, although less direct, emerges from the physiological nature of neural data and its connection to the neurobiological development of the individual. This connection highlights how neurodata, much like genetic data, can contain latent markers of identity that become sensitive only through interpretation. Both types of data originate from deeply embedded biological structures and acquire their personal significance through analytical processes.

The GDPR defines genetic data in article 4 (13):

> 'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question; [86]

Although the GDPR does not expressly define a relationship between neurodata and genetic data; neurodata, especially when derived from investigations such as fMRI or deep neuromodulation, may contain information about neurophysiological traits that are susceptible to heritability or that develop over a lifetime in close relation to the individual's genetic makeup. However, the qualification of neurodata as biometric or genetic data presents some critical issues. First, from a systematic point of view, the GDPR does not expressly include neurodata among the special categories, resulting in a certain level of legal ambiguity. In addition, not all brain data collected through neurotechnology has an immediate identification purpose. Some commercial devices, for example, are designed to monitor attentional states or stress levels without pursuing user identification. In such cases, the processing may not technically fall under the definition of biometric data, although there are views that identification purpose is not always necessary for the application of Article 9 GDPR[87]. These interpretive ambiguities show

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[86] GDPR, art. 4 (13).

[87] 'Not all biometric data is 'special category biometric data'. This only applies if you use it, or intend to use it, to uniquely identify someone. However, even if this is not your purpose, the biometric data you process may still be considered another type of special category information. For example, you could use biometric data to infer someone's racial or ethnic origin or consider it as health data'.
Information Commissioner's Office, *Key Data Protection Concepts in Biometric Recognition* (2024) https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/lawful-basis/biometric-data-guidance-biometric-recognition/key-data-protection-concepts/ accessed 18 July 2025.

how the regulatory framing of neurodata oscillates between existing definitions and new regulatory requirements.

The difficulty of rigidly applying the GDPR's traditional categories is exacerbated when considering the evolution of technological capabilities and the increasing possibility of identification through brain data, even in the absence of explicit intentionality. It is precisely on this point that a broader reflection on the practical and prospective implications of individual identifiability through neurodata is triggered.

Concerning this issue, Greenberg et al argue:

> Although identifying individuals based solely on their collected personal neurodata is likely a difficult proposition, such identification has been shown to be possible with relatively little data (less than 30 seconds-worth) within a lab setting, and some experts believe that such identification is feasible if not today, then in the near-term.[88]

This technical possibility, coupled with the tendency for neurotechnology to expand into non-health care contexts, such as entertainment, education or marketing, calls for deeper regulatory reflection on the need to accord neurodata equivalent protection to biometric and genetic data, regardless of the context or purpose of processing.

In conclusion, although the GDPR provides a useful framework for framing neurodata within the existing concepts of biometric and genetic data, the question remains open as to whether there is a need for an explicit and autonomous recognition of this new category of data, capable of providing adequate protection considering its unique characteristics and the rapid technological evolution that allows its increasingly pervasive.

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[88] Future of Privacy Forum and IBM Policy Lab, *Privacy and the Connected Mind: Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces* (Future of Privacy Forum 2021) https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf ‘9.

1.5 Potential risks of neurotechnology

1.5.1. Risks to mental privacy

As examined in the previous chapters, the rapid advancement of neurotechnologies has introduced a set of unprecedented challenges to fundamental rights and freedoms, chief among them the right to privacy. While traditional privacy principles mainly focused on protecting individuals from unauthorized access to their personal data, the emergence of devices capable of interfacing directly with the brain, such as non-invasive brain-computer interfaces (BCIs), neuroimaging technologies, and cognitive monitoring systems, demands a deeper reconceptualization of privacy itself.

This reconceptualization implies a shift from merely safeguarding the outward expression of thought to protecting its very formation. As already introduced in section 1.4.1, as neurotechnologies make it possible to access and interpret neural signals prior to any voluntary act of expression, the legal framework must evolve to shield not only the forum externum but also the forum internum, the inner, pre-reflective space where thoughts, emotions, and intentions originate. Mental privacy, in this light, demands protections that encompass the genetic moment of thought itself, before it is ever externalized or articulated. In this context, the concept of mental privacy has gained growing relevance in academic, ethical, and legal discussions. Mental privacy refers to an individual's right to control not only who accesses their neural data, but also what can be inferred from it regarding their thoughts, emotions, and mental processes. Essentially, 'the concept of mental privacy can be defined as the principle that subjects should have control over the access to their own neural data and to the information about the mental processes and states that can be obtained by analyzing it'[89]. This definition reveals the layered nature of the threat: neurotechnologies do not merely reveal surface-level information but penetrate the core of what we consider the inner self, our mental life.

This makes neurotechnological intrusions categorically different from traditional privacy violations. Mental states, unlike passwords or geolocation data, are not typically generated and shared voluntarily or even consciously. One of the fundamental principles

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[89] Pablo López-Silva, Abel Wajnerman-Paz and Fruzsina Molnár-Gábor, 'Neurotechnological Applications and the Protection of Mental Privacy: An Assessment of Risks' (2024) 17 *Neuroethics* 31.

of privacy in a liberal society is the individual's capacity to decide what to reveal and what to conceal. This decision-making is not only a right but a cognitive process intrinsic to human dignity. In this sense, the concept of privacy 'depends on this cognitive process of rationally filtering and selectively sharing information about us. Neurotechnological mind-reading may be specially threatening for privacy precisely because it bypasses this fundamental filtering process'[90]. The implication is profound: neurotechnological intrusions might short-circuit our mental autonomy, extracting data before the individual even has a chance to interpret it for themselves. The potential consequences of such capabilities extend beyond theoretical concerns and into tangible social harms. As neural data and cognitive biometric markers become integrated into human resource systems, educational platforms, and security screening, a new form of digital profiling emerges. The risk is not simply that this data might be misused accidentally, but that it will be systematically employed in contexts of judgment and evaluation. For instance, 'if neurocognitive profiles based on neural data begin to be used as a means to make decisions about hiring, promoting or firing employees, then there is the risk that these decisions are made on the basis of irrelevant information, leading to arbitrary discrimination'[91]. This type of misuse threatens not only fairness but also the epistemic basis upon which decisions about people are made, allowing machine inferences to override contextual human judgment.

Compounding the issue is the highly inferential nature of neural data. This kind of data, such as EEG patterns, eye movements, or brain activation signals, may initially seem devoid of meaning, but when processed by increasingly sophisticated algorithms, these data points become powerful tools for deducing mental states, preferences, and behavioral tendencies. Crucially, 'even de-identified or aggregated, cognitive biometric data can still pose risks to mental privacy. When such data are combined with other data sources, there is a potential for re-identification or for sensitive inferences to be made about individuals' mental states '[92]. In other words, anonymization alone does not guarantee safety; the very structure of the data renders it sensitive by default.

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[90] Abel Wajnerman Paz, 'Is Mental Privacy a Component of Personal Identity?' (2021) 15 *Frontiers in Human Neuroscience,* 773441, 2.

[91] López-Silva, Wajnerman-Paz and Molnár-Gábor, (n 89).

[92] Patrick Magee, Marcello Ienca and Nita Farahany, 'Beyond neural data: Cognitive biometrics and mental privacy' (2024) 112 *Neuron* 3020.

The problem is exacerbated by the opacity of data practices in the commercial sector. Neurotechnology is not confined to academic laboratories or clinical trials, it is increasingly embedded in consumer products such as wearable devices, productivity tools, and mental health apps. In these contexts, users are often unaware of how their data are collected, stored, and processed: transparency is minimal, and safeguards are often nonexistent. 'Most companies provide little information about how the data they collect is stored. … These limited disclosures provide consumers with little assurance that sensitive insights obtained from their cognitive biometric data will be kept confidential'[93]. This lack of accountability leaves users vulnerable not just to external breaches, but also to internal abuses of trust.

A particularly pressing concern in this context is the widespread use of mental health apps, which collect and process highly sensitive data under conditions often lacking adequate transparency and security. Empirical research has shown that 'most apps pose linkability, identifiability, and detectability threats'[94] making it possible for third parties to re-identify users and infer their mental health conditions based on behavioral data and metadata alone. Alarmingly, many apps transmit personal information in plain text, employ weak cryptographic protocols, and share user data with advertising services and data brokers without proper user awareness. The same study, which focused on the privacy practices of top-ranked mental health apps, found that '24/27 [mental health] app privacy policies were found to require at least college-level education to understand them'[95] suggesting a significant barrier to informed consent and increasing the risk of unintentional disclosure of sensitive mental states. As digital mental health tools continue to grow in popularity, particularly among adolescents and vulnerable populations, concerns about the long-term visibility and permanence of their digital footprints remain acute. These vulnerabilities are further exacerbated by the lack of clarity around the business models of app developers. In such a landscape, mental privacy is threatened not only by malicious attacks, but also by structural opacity and normative gaps in how these technologies are designed and deployed.

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[93] ibid 3019.

[94] Leonardo Horn Iwaya and others, 'On the privacy of mental health apps: An empirical investigation and its implications for app development' (2023) 28 *Empirical Software Engineering* 3.

[95] ibid.

These concerns highlight how threats to mental privacy are not limited to invasive hardware or clinical neurotechnologies but are increasingly embedded in the everyday digital tools people use to manage their mental health. The erosion of mental privacy through such mundane, yet pervasive, channels underscore the need to frame this issue within a broader ethical context. What is at stake is not simply the misuse of personal information, but the integrity of the mental space itself, the core from which identity, agency, and autonomy emerge. In this sense, risks to mental privacy directly implicate the individual’s right to informational self-determination, the ability to control how and by whom one's mental states are accessed, interpreted, and used. When the data subject is a minor, the potential impact of these risks becomes especially concerning, for example, because their cognitive and emotional development is still in progress, and they may lack the full capacity to understand or consent to such intrusions. The asymmetry of power and knowledge in these contexts amplifies the potential for exploitation and long-term harm.

1.5.2. Manipulation of behavior and personal identity

It is now clear how rapid advancement of neurotechnologies has opened unprecedented possibilities for understanding and interacting with the human brain. From brain-computer interfaces to non-invasive brain stimulation and optogenetics, these tools are no longer confined to experimental neuroscience but are gradually entering consumer markets, military strategies, and educational platforms. While the benefits are considerable, like offering hope for the treatment of neuropsychiatric disorders and for enhancing cognitive functions, the risks are equally significant, particularly concerning the manipulation of behavior and the integrity of personal identity.

One of the clearest areas of concern arises from non-invasive brain stimulation technologies such as transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS). These tools have been shown to influence not just perception or attention, but also moral reasoning, emotional state, and social behavior. As documented in a comprehensive review, ‘rTMS can also influence judgment of attempted harms (i.e., negative beliefs) as being less morally forbidden and more morally permissible … and can increase probability of utilitarian responses, especially in high-conflict dilemmas'[96]. This ability to subtly shift moral judgments raises profound ethical questions: if the very principles by which we distinguish right from wrong can be externally modulated, where do we draw the line between enhancement and manipulation?

The potential for direct intervention into emotional states is no less troubling. This issue emerges particularly in the application of rTMS over the prefrontal cortex, where subjects reported overwhelming emotional responses: 'early work shows that rTMS applied over the prefrontal cortex … led to dysphoric reaction to the point of overwhelming sadness and crying'[97]. Such reactions, when induced without proper clinical supervision or for non-therapeutic purposes, may pose risks to psychological stability and self-perception. Manipulating brain function is not just a technical act, it is an intervention in the substrate of human identity. The concerns deepen when considering optogenetics, a method that enables millisecond-precision control over neural activity via genetically encoded light-sensitive proteins. This technology has been used to trigger or suppress specific behaviors in animal models by activating particular neurons associated with reward, fear, or motivation. Researchers 'identified the stimulus patterns that appeared to drive a sense of reward for the animals. In the absence of any other cue or reward, mice chose to spend more time in places where they had received particular kinds of bursts of activity in their dopamine neurons'[98]. Such findings illustrate the feasibility of artificially inducing desires or habits, a mechanism that, if applied to humans, could bypass volition and reshape behavior without the subject's awareness.

These troubling prospects are also emerging in connection with AI systems: recent advances in neurotechnology are increasingly merging with algorithmic systems that do more than simply collect data; they analyze, predict, and shape human behavior in real time. This convergence introduces a critical risk: the covert manipulation of individual preferences, decisions, and emotional states through systems designed not to support autonomy, but to steer it toward desired outcomes. One of the most sophisticated

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[96] Shirley Fecteau, 'Influencing Human Behavior with Noninvasive Brain Stimulation: Direct Human Brain Manipulation Revisited' (2023) 29 *The Neuroscientist* no 3, 324.

[97] ibid.

[98] Karl Deisseroth, 'Controlling the Brain with Light' (2010) 303 *Scientific American* no 5, 54.

mechanisms within this landscape is hypernudging. Unlike traditional nudges[99], which aim to influence behavior through static modifications in decision environments, hypernudges operate dynamically. They rely on real-time data streams and adaptive algorithms that personalize digital environments according to a user's interactions. As explained in the literature:

> the hypernudge allows nudges to operate dynamically via real-time data feeds used to personalize the outputs according to the user's actions. This mechanism is a continuous feedback loop. The output feeds the input, constantly reconfiguring the choice architecture in real-time. [100]

In such a system, users are continuously monitored and their experiences subtly reshaped without clear boundaries between choice and influence. Over time, this adaptive loop narrows the space of perceived options, not through coercion, but by design. These systems are built upon refined cognitive profiling methods. Behavioral traces (clicks, pauses, navigation paths, even biometric signals) are used to infer internal states and intentions. More importantly, they are used to induce predictable reactions: 'the knowledge acquired is used to modify and induce attitudes and behaviors, modifying the online experience according to the acquired cognitive profile of the individual'[101]. The individual becomes the subject of a predictive model designed to guide them toward specific behavioral outcomes, with little awareness of the forces shaping their choices.
This form of influence cannot be equated with traditional human persuasion. As the same source emphasizes, 'algorithmic-driven manipulative techniques are different from any form of persuasion humans can possibly exercise or be subject to"[102]. Rather than presenting arguments or appeals, these techniques manipulate the structure of choices themselves, invisibly framing the user's decisions by filtering what is shown, how it is shown, and when.

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[99] The theory of nudges, which aims to steer decisions through subtle changes in the choice architecture while preserving individual freedom, was introduced by Richard H Thaler and Cass R Sunstein in *Nudge: Improving Decisions About Health, Wealth and Happiness* (Yale UP 2008).

[100] Stefano Faraoni, 'Persuasive Technology and computational manipulation: hypernudging out of mental self-determination' (2023) 6 *Frontiers in Artificial Intelligence* (Technology and Law), 4.

[101] ibid 2.

[102] ibid.

1.6 Ethical and philosophical aspects of neuroscience and neurotechnology

1.6.1 Neuroethics: definition and main dilemmas

Neuroethics has emerged as a vital interdisciplinary field in response to the growing influence of neuroscience and neurotechnology on human life; it sits at the intersection of ethics, science, and philosophy, grappling with the consequences of our increasing ability to observe, interpret, and alter the brain. The concept of neuroethics took shape in the early 21st century as the need emerged to more systematically address the ethical and social dimensions raised by advances in brain science. Although discussions on the moral implications of neuroscience were already present in bioethical and philosophical debate, the formal establishment of neuroethics as a distinct field is widely associated with William Safire. In 2002, during the Dana Foundation conference *Neuroethics: Mapping the Field*, Safire defined neuroethics as 'the examination of what is right and wrong, good and bad about the treatment of, perfection of, or unwelcome invasion of and worrisome manipulation of the human brain'[103] thereby setting the stage for a more cohesive and interdisciplinary approach to these issues. This field evolved to be broadly concerned with both the ethical implications of neuroscientific applications and the foundational questions they raise about human nature. In this sense, neuroethics exhibits a dual nature; indeed, some of the dilemmas it presents have a 'practical nature, concerning the applications of neurotechnology and their likely implications for individuals and society. Others are more philosophical, concerning the way we think about ourselves as persons, moral agents and spiritual beings'[104].

From the practical point of view, one of the most immediate ethical concerns in neuroethics is the issue of cognitive enhancement. Technologies originally developed for therapeutic purposes are now being explored for their potential to boost cognitive performance in healthy individuals. This raises profound questions about autonomy, consent, and social equity: if such enhancements become widespread, those who choose

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[103] William Safire, 'Visions for a New Field of "Neuroethics"' in Steven J Marcus (ed), *Neuroethics: Mapping the Field* (Dana Press 2002) 5.

[104] Martha J Farah, 'Neuroethics: the practical and the philosophical' (2005) 9 *Trends in Cognitive Sciences* no 1, 34.

not to use them may be disadvantaged. As observed, ‘the freedom to remain unenhanced may be difficult to maintain in a society where one’s competition is using enhancement’[105]. At the same time, the use of neurotechnological interventions to alter mood, temperament, or even sexual performance leads us to question the authenticity of the self we project to the world. In this regard, some authors wonder: ‘are we treating people (including ourselves) as objects if we chemically upgrade their cognition, temperament or sexual performance?’[106]

These concerns are further intensified by the growing awareness that identity and personhood are often viewed through the lens of neurobiology. In contemporary culture, there is a tendency to attribute personal essence directly to brain structure and function, a view sometimes called neuroessentialism[107]. As it is commonly believed, ‘many of us overtly or covertly believe in a kind of “neuroessentialism,” that our brains define who we are, even more than do our genes’[108]. This belief gives rise to difficult questions: if the brain defines who we are, then how should we ethically evaluate medical or technological interventions that modify its function? Critics have emphasized that such a perspective promotes a reductive understanding of the human being and obscures the broader social, relational, and embodied dimensions of subjectivity. Racine and Sample have described this as a form of neuroscientism, defined as ‘a belief in the capacity of neuroscience to reveal the socle of moral decisionmaking, because neuroscience reveals the true nature of things’[109]. This epistemological privileging of brain science risks marginalizing other disciplinary perspectives, such as moral psychology or anthropology, which can offer equally valuable insights into human morality. Against this backdrop, Racine and Sample argue for a pragmatist reconstruction of neuroethics: one that remains open to empirical contributions without reducing ethical inquiry to neurological data. As they contend, ‘the promising and often profound insights from neuroscientific studies of

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[105] ibid 37.

[106] ibid.

[107] The term neuroessentialism was first introduced by Eric Racine, Ofek Bar-Ilan and Judy Illes in ‘fMRI in the Public Eye’ (2005) 6 *Nature Reviews Neuroscience* 159, where they describe the tendency to identify the brain as the seat of personal identity, referring to it as a “secular equivalent of the soul”. The concept was later developed by Peter B Reiner in ‘The Rise of Neuroessentialism’ in Judy Illes and Barbara J Sahakian (eds), *Oxford Handbook of Neuroethics* (OUP 2011), where he discusses how this view influences social practices and the perception of the self.

[108] Adina L Roskies, ‘Neuroethics for the New Millennium’ (2002) 35 *Neuron* no 1, 22.

[109] Eric Racine and Matthew Sample, ‘Two Problematic Foundations of Neuroethics and Pragmatist Reconstructions’ (2018) 27 *Cambridge Quarterly of Healthcare Ethics* 568.

morality are no more foundational than knowledge generated by other disciplines such as psychology, sociology, or anthropology'[110]. Ethics, in their view, should remain an interdisciplinary space oriented toward solving real-world problems, not a domain governed by neuroscientific authority alone.

From a different yet complementary angle, Ludwig Weh critically examines the persistence of cartesian dualism in both neuroscience and AI, showing how it reinforces the notion of a disembodied mind abstracted from its social and corporeal context. He notes that 'machine-based "intelligence" cannot evade its materiality within a dualist view … of assuming the possibility of a mechanical model of mental activity'[111]. Such dualistic abstraction, when applied to neurotechnologies, tends to obscure the embodied, historically situated character of cognition. Instead, Weh calls for an ethical approach that reasserts the human as an embodied being, shaped by physical and social interaction. He stresses the need for 'an effective science ethics enabling widespread and accessible social discourse'[112]. By framing AI and neurotechnology within this material and relational context, Weh's model avoids reducing ethical issues to purely technical challenges and promotes a more comprehensive, human-centered discourse.

This embodied and relational perspective has significant implications not only for how we conceptualize the mind, but also for how we approach the ethical responsibilities tied to neuroscientific innovation. The need to move beyond abstract models becomes especially pressing when considering the concrete ways in which neurotechnologies interact with human identity and lived experience. Bridging theory and practice, the ethical challenges raised by dualistic assumptions must now be addressed within the everyday contexts of scientific training, clinical use, and technological development. In this regard, education and critical reflection must accompany technical progress to ensure that researchers and practitioners remain attentive to their work's social and moral dimensions. In this context, 'neuroethics scholars and neuroscientists who have specific neuroethics interests have an important role in teaching ethical awareness to young trainees, and in the application of critical ethical thinking to the scientific process'[113].

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[110] ibid 570.

[111] João Teixeira, *Computational Complexity and Philosophical Dualism* (1998), quoted in Ludwig Weh, 'An Integrated Embodiment Concept Combines Neuroethics and AI Ethics' (2024) 18 *Nanoethics* 5.

[112] ibid.

[113] Judy Illes and Stephanie J Bird, 'Neuroethics: A Modern Context for Ethics in Neuroscience' (2006) 29(9) *Trends in Neurosciences* 511.

Ethical literacy is not an optional skill in the neuroscientific enterprise: it represents a necessary foundation for responsible innovation.

From the above analysis, it emerges that neuroethics represents more than an auxiliary branch of bioethics; it is a critical framework for navigating the ethical, legal, and societal implications of technologies that touch the very core of who we really are. As neurotechnologies become increasingly capable of not only observing but also modifying cognitive, emotional, and behavioral states, the line between treatment and transformation begins to blur. This shift forces us to reconsider foundational concepts such as autonomy, responsibility, and identity.

The dilemmas posed by cognitive enhancement, neuroessentialist assumptions, and the integration of AI into neurotechnological systems are not confined to laboratories or academic discussions: whether these technologies are used to improve productivity, monitor behavior, or shape decision-making, they raise profound questions about the conditions under which human freedom and authenticity can be preserved.

At the same time, the societal consequences of unequal access to neuroenhancement or algorithmically guided neuro-interventions risk exacerbating existing inequalities. The pressure to conform to enhanced standards of performance or to delegate decision-making to intelligent systems could undermine democratic values and social cohesion.

Neuroethics must therefore serve a dual role: it must guide the responsible development and use of neurotechnologies through well-defined ethical and legal principles, and it must also foster a broader cultural reflection on what kind of future we want to inhabit. It should engage not only scientists and policymakers, but also educators, patients, citizens, and communities: by fostering dialogue across disciplines and cultures, neuroethics can help ensure that the promises of neuroscience do not come at the cost of our most basic human rights.

1.6.2 The right to mental self-determination

As examined in the previous section, in the expanding landscape of neuroscience and neurotechnology, the human mind emerges not only as an object of scientific interest but as a site of profound ethical and legal vulnerability. Technologies capable of modulating affect, belief, desire, and volition raise the pressing question: how can we ensure that individuals remain sovereign over the content and structure of their own mental lives? This question could find its response in the concept of mental self-determination, which must now be articulated and defended not as a speculative moral ideal, but as a cornerstone of personhood in the age of brain intervention.

Mental self-determination refers to the right of individuals to form attitudes, beliefs, intentions, and desires free from non-consensual influence. This concept is closely aligned with what is often described in philosophical literature as mental autonomy: as William Ratoff explains, 'the right to mental autonomy just is the right to form attitudes in light of reasons'[114] and any attempt to influence mental content that bypasses rational engagement (such as subliminal messaging, coercive neurostimulation, or pharmacological manipulation) violates this right. Thus, the ethical difference between persuasion and manipulation lies in the method of influence: while the former appeals to reason, the latter bypasses it. In this perspective, the right to mental self-determination must also encompass elements that are not under conscious control. Even subconscious or automatic states '"belong" to the individual; in fact, they constitute large part of his character'[115] and deserve protection from external manipulation. This broader view of mental sovereignty implies that integrity is not limited to the ability to deliberate but extends to those involuntary mental elements that form the fabric of personal identity.

Indeed, identity is a recurring theme in discussions about mental self-determination. The principle of psychological continuity, a concept developed and refined in contemporary philosophy by Parfit[116] and embraced by Ienca and Andorno[117], suggests that personal identity is preserved through a chain of psychological connections: beliefs, desires, intentions, and memories linked over time. Such a view underscores the deep connection between mental integrity and the continuity of the self. When neurotechnologies interfere with these psychological links, they do not merely alter isolated mental state, they threaten the very narrative coherence through which individuals experience themselves as unified,

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[114] William Ratoff, 'The Right to Mental Autonomy: Its Nature and Scope' (2024) 27(2) *Journal of Ethics and Social Philosophy* 249.

[115] Jan Christoph Bublitz, 'If Man's True Palace Is His Mind, What Is Its Adequate Protection? On a Right to Mental Self-Determination and Limits of Interventions into Other Minds' in Bibi van den Berg and Laura Klaming (eds), *Technologies on the Stand: Legal and Ethical Questions in Neuroscience and Robotics* (Wolf Legal Publishers 2011).

[116] See Derek Parfit, *Reasons and Persons* (Oxford University Press 1984).

[117] See Marcello Ienca and Roberto Andorno, 'Towards New Human Rights in the Age of Neuroscience and Neurotechnology' (2017) 13 *Life Sciences, Society and Policy* 5.

enduring persons. These important concerns raise urgent issues about interventions that could potentially reconfigure the entire structure of selfhood. ‘Personality is a conglomerate of interwoven mental states’[118], and any manipulation of thoughts, emotions, or preferences risks undermining the very sense of personal identity that legal frameworks are meant to uphold.

What complicates these issues further is the fact that the legal system has yet to catch up with these developments; at present, no jurisdiction has articulated a coherent legal framework governing conduct that directly targets or interferes with mental processes, despite the existence of normative traditions such as freedom of thought and conscience. The forum internum, the inner mental space where beliefs and intentions are formed, enjoys absolute protection in theory, yet remains underdefined in practice. Consider the use of fMRI-based lie detection in court, or the prospect of moral enhancement for prisoners: while framed as therapeutic or rehabilitative, such interventions may suppress the capacity for genuine moral reflection. Even if such measures produce socially desirable outcomes, their potential use ‘suggests that the authorities consider the offender’s existing character to be so comprehensively morally inadequate that positive moral change is unlikely to emerge from it’[119], a cost too high for a society committed to respect for persons.

Thus, the right to mental self-determination emerges not only as a safeguard against abusive interventions, but as a foundational condition for treating individuals as autonomous agents. Liberal legal systems are built upon the presumption that citizens are capable of regulating their conduct through reason, and that they remain free to form and revise their beliefs without coercion. In this regard, ‘governments may promote but cannot demand such socially desirable transformations’[120] of a person’s mental or moral character. Any attempt to override this principle through direct neurotechnological interventions risks violating core liberal values and disrupting the inner autonomy that legal responsibility presupposes.

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[118] Bublitz (n 115) 106.

[119] Elizabeth Shaw, ‘Free Will, Punishment and Neurotechnologies’ in Bibi van den Berg and Laura Klaming (eds), *Technologies on the Stand: Legal and Ethical Questions in Neuroscience and Robotics* (Wolf Legal Publishers 2011), 200.

[120] Jan Christoph Bublitz, ‘“The Soul Is the Prison of the Body”: Mandatory Moral Enhancement, Punishment and Rights Against Neuro-Rehabilitation’ in David Birks and Thomas Douglas (eds), *Treatment for Crime: Philosophical Essays on Neurointerventions in Criminal Justice* (OUP 2018), 18.

Without the protection of mental self-determination, the state could no longer draw a principled line between persuasion and coercion, between education and manipulation.

In sum, the right to mental self-determination affirms that individuals are not programmable entities, but reflective beings capable of deliberation, dissent, and change. As neurotechnology expands the tools available to influence thought, emotion, and intention, this right becomes the ethical boundary for legitimate state action. Respecting this boundary is essential not only for the individual's dignity, but for preserving the very notion of legal personhood upon which democratic institutions depend.

As we now transition to the next chapter, dedicated to the legal regulation of neurodata and neurotechnological applications, it becomes clear that ethical commitments must be translated into normative frameworks. The rights discussed here, including freedom of thought, personality, and mental integrity, demand concrete legal articulation and enforcement. The task ahead is to examine how existing legal instruments, along with emerging proposals for neurorights, can be mobilized to ensure that the mind remains a protected space, one that cannot be accessed, altered, or appropriated without consent.

Chapter 2: Neurorights and Fundamental Rights

2.1 Origin of the concept of neurorights

2.1.1 From freedom of thought to neurorights

Throughout history, the philosophical and legal recognition of mental autonomy has evolved through the concepts of freedom of thought and freedom of conscience, principles now embedded at the heart of modern democratic societies. From early notions of spiritual autonomy to Enlightenment ideals of rational self-determination, the inner realm of the human mind has been regarded as sacred, deserving of protection from intrusion and coercion. In the 17th century, John Milton, in his impassioned defense of unlicensed printing in *Areopagitica* (1644), famously asserted that the liberty 'to know, to utter, and to argue freely according to conscience'[121] stands above all other freedoms. Around the same time, Baruch Spinoza, in his *Theological-Political Treatise* (1670), argued that 'in a free state, everyone is allowed to think what they wish and to say what they think'[122], anticipating a vision of civil liberty grounded in intellectual freedom and tolerance.

The Enlightenment later solidified these ideas into a broader philosophical and political program. Immanuel Kant, in his 1784 essay *What is Enlightenment?* exhorted individuals to 'have courage to use [their] own understanding'[123] (*sapere aude*[124]), defining freedom not merely as external independence, but as the capacity for autonomous thought. This view positioned the mind as the cornerstone of moral agency and public reason. Building on this foundation, John Stuart Mill, in *On Liberty* (1859), argued that the sovereignty of the individual over 'his own body and mind'[125] is essential for both personal development

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[121] John Milton, *Areopagitica: A Speech for the Liberty of Unlicenc'd Printing to the Parlament of England* (1644) https://www.saylor.org/site/wp-content/uploads/2011/02/Areopagitica.pdf (cur Thomas H Luxon).

[122] Baruch Spinoza, *Theological-Political Treatise* (Michael Silverthorne tr, Jonathan Israel ed, Cambridge University Press 2007) 250.

[123] Immanuel Kant, *An Answer to the Question: What is Enlightenment?* (Ted Humphrey tr, Hackett Publishing 1992) 1.

[124] Kant recalls the Latin maxim *sapere aude* ("dare to know"), originally formulated by Horace (*Epistles* I.2.40), to express the Enlightenment ideal of intellectual autonomy and the individual's duty to think independently.

[125] John Stuart Mill, *On Liberty* (Hackett Publishing 1978) 22 https://archive.org/details/onliberty00inmill accessed 12 June 2025.

and societal progress. For Mill, liberty of thought and expression was not only a right but a necessary condition for truth, innovation, and human flourishing.

These classical formulations laid the groundwork for the contemporary understanding of cognitive liberty, the idea that individuals must remain free to think, feel, and decide without undue influence or surveillance.

With the rapid development of neuroscience and brain-related technologies, these long-standing philosophical commitments have entered into a new phase of scrutiny. The cognitive interiority that once seemed inaccessible has become, at least partially, observable, measurable, and even modifiable. Technologies capable of reading brain signals, altering neural activity, or decoding emotional states, once the domain of science fiction, are today the focus of experimental and commercial efforts across a variety of sectors, from medicine to defense to consumer electronics.

This transformation has given rise to several new academic fields. Neuroethics, which emerged in the early 2000s[126], seeks to examine the ethical implications of accessing or intervening in the brain. It addresses questions of moral responsibility, personal identity, mental enhancement, and the potential for manipulation or coercion through neural means. Closely related is neurolaw[127], which considers how findings from neuroscience might influence legal reasoning, criminal justice, and rights protection. Both fields reflect a growing need to revisit fundamental legal and ethical frameworks in light of scientific capabilities that challenge traditional notions of free will, consent, and culpability.

As detailed in the previous chapter, neurotechnologies have reached a level of sophistication that calls for a more structured legal and normative response. The ability to interface directly with the brain, through non-invasive devices or implantable neural interfaces, raises complex questions about mental privacy, cognitive liberty, and the potential for discriminatory or exploitative uses of brain data. These concerns are no longer merely speculative but are increasingly discussed in policy circles, regulatory debates, and constitutional reforms.

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[126] See section 1.6.1

[127] The term "neurolaw" began to circulate in the early 1990s, notably with the work of J Sherrod Taylor, who explored the implications of neuroscience for legal responsibility and adjudication. Although Taylor is often credited with first using the term, a more thorough reconstruction of its historical development is provided by Francis X Shen, who identifies four key moments in the emergence of neurolaw as a field, including the early contributions of Taylor and others. See Francis X Shen, 'The Overlooked History of Neurolaw' (2016) 85 *Fordham Law Review* 667 https://ir.lawnet.fordham.edu/flr/vol85/iss2/13.

It is in this environment that the concept of neurorights has emerged. While their precise definitions and scopes are still under academic and legislative development, neurorights aim to translate classical protections, such as privacy, freedom, and equality, into forms that apply to the brain itself. The remainder of this chapter will explore the academic origins of this concept, examining the early scholarly proposals that recognized the need for legal safeguards in response to the profound ethical and societal challenges posed by emerging brain technologies.

2.1.2 Academic origins of neurorights

The concept of neurorights has emerged in recent years as a critical response to the growing capabilities of neuroscience and neurotechnology, which increasingly allow access to the most private domain of human existence: the mind. Although the term neurorights itself is relatively new, the academic groundwork for this concept was laid gradually, through a multidisciplinary dialogue involving legal theory, ethics, neuroscience, and philosophy. The intellectual origins of neurorights reflect a deeper concern with safeguarding mental autonomy, especially in light of technologies capable of decoding or interfering with neural activity.

One of the earliest conceptual foundations of this field is the notion of cognitive liberty. This principle was articulated and developed by Wrye Sententia and Richard Glen Boire, co-founders of the Center for Cognitive Liberty and Ethics, who began exploring the concept in the late 1990s and early 2000s in response to the expanding capabilities of neurotechnology and psychopharmacology. They conceptualized cognitive liberty as a necessary extension of traditional freedoms in an era where the mind itself could be accessed, influenced, or modified by external agents. As Sententia defined it, 'cognitive liberty is every person's fundamental right to think independently, to use the full spectrum of his or her mind, and to have autonomy over his or her own brain chemistry'[128]. This definition situates cognitive liberty not only as a negative freedom (freedom from interference) but also as a positive capacity for self-directed mental exploration and neurocognitive self-determination.

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[128] Wrye Sententia, 'Neuroethical Considerations: Cognitive Liberty and Converging Technologies for Improving Human Cognition' (2004) 1013 *Annals of the New York Academy of Sciences* 223

Boire, adopting a legal-philosophical stance, emphasized the importance of identifying threats to mental freedom as a first step in constructing any defensible normative framework. He observed that ‘part of elucidating a theory of cognitive liberty is simply recognizing when free cognition is being infringed’[129].In this sense, cognitive liberty serves as a diagnostic lens through which to interpret the ethical implications of neuroscience, neuroenhancement, and state or corporate regulation of cognitive processes. Although their work was often more advocacy-driven than academically formalized, Sententia and Boire introduced a conceptual vocabulary that would become foundational for later scholarly and policy-oriented discussions on neurorights.

Building on this foundation, Christoph Bublitz offered a legal interpretation of cognitive liberty in a series of articles between 2014 and 2016. He argued for the legal recognition of mental integrity as a form of protection against unauthorized neuro-intervention. In this sense, he acknowledged the need for a nuanced legal framework that distinguishes between varying degrees of mental interference. As he explains, ‘interventions that alter opinions, modify decisions, or severely undermine thinking capacities may run afoul of the core guarantee of freedom of thought, whereas minor interventions might not necessarily do so.[130]. His contributions helped translate abstract ethical concerns into tangible legal concepts, reinforcing the legitimacy of neurorights as a potential category within human rights law.

Around the same time, Nita Farahany was advancing her own influential arguments on cognitive liberty and mental privacy. As early as 2012[131], she warned of the unprecedented risks posed by brain-monitoring technologies, in particular, by shedding light on the challenges that neurotechnological and neuroscientific advances pose to the right against self-incrimination. Her later work, including her 2023 book *The Battle for Your Brain*[132], expanded on these concerns and argued that existing legal frameworks are inadequate to protect individuals from the emerging threat of cognitive surveillance. Farahany’s work

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[129] Craig Boire, ‘On Cognitive Liberty, Part I’ (1999/2000) 1 *Journal of Cognitive Liberty & Ethics* 7 http://www.cognitiveliberty.org/ccle1/1jcl/1jcl7.htm accessed 20 July 2025.

[130] Christoph Bublitz, ‘Cognitive Liberty and the International Right to Freedom of Thought’ in Jens Clausen and Neil Levy (eds), *Handbook of Neuroethics* (Springer 2015) 1322.

[131] See Nita A Farahany, ‘Incriminating Thoughts’ (2012) 64 *Stanford Law Review* 351 https://scholarship.law.duke.edu/faculty_scholarship/2651 accessed 20 July 2025.

[132] Nita A Farahany, *The Battle for Your Brain: Defending the Right to Think Freely in the Age of Neurotechnology* (St Martin’s Press 2023).

situates neurorights within broader debates about civil liberties, human dignity, and technological power.

This growing body of interdisciplinary scholarship laid the essential conceptual and normative groundwork for what would soon become a more explicitly defined legal category. The first fully articulated academic proposal explicitly using the term *neurorights* appeared in fact in 2017, when Marcello Ienca and Roberto Andorno published their seminal article *Towards new human rights in the age of neuroscience and neurotechnology*[133]. There, they identified a set of core rights they believed were necessary to safeguard individuals in the face of neurotechnological advances: cognitive liberty, mental privacy, mental integrity, and psychological continuity. Their article (which will be examined in more detail in Section 2.2) argued that these dimensions of mental life, once merely theoretical concerns, were now vulnerable to real-world interference and manipulation, and thus required explicit legal recognition. The authors positioned neurorights not as a radical departure from traditional human rights, but rather as a necessary evolution of existing principles adapted to new technological realities.

Almost concurrently, Rafael Yuste, Sara Goering, and other members of the Morningside Group[134] published an article entitled '*Four ethical priorities for neurotechnologies and AI'*[135]. Their ethical framework aligned closely with the emerging discourse on neurorights, calling for the protection of privacy, agency, personal identity, equitable access to enhancement technologies, and safeguards against algorithmic bias. Yuste would go on to become one of the most vocal advocates for the legal institutionalization of neurorights, playing a central role in the establishment of the NeuroRights Initiative at Columbia University[136]. The Initiative advanced a more systematic codification of neurorights, explicitly identifying five core principles: cognitive liberty, mental privacy, personal identity, free will, and fair access to mental augmentation, often including

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[133] Marcello Ienca and Roberto Andorno, 'Towards New Human Rights in the Age of Neuroscience and Neurotechnology' (2017) 13 *Life Sciences, Society and Policy* 5.

[134] The Morningside Group is an international consortium of neuroscientists, neurotechnologists, ethicists, clinicians, and AI researchers, including members from academic institutions, global brain initiatives, and companies such as Google and Kernel, who convened in 2017 to address the ethical implications of neurotechnologies and machine intelligence.

[135] Rafael Yuste and others, '*Four Ethical Priorities for Neurotechnologies and AI'* (2017) 551 *Nature* 159.

[136] The NeuroRights Initiative, (which later evolved into the NeuroRights Foundation) based at Columbia University, is a multidisciplinary project that aims to promote the recognition and protection of neurorights through scientific research, policy development, and international advocacy in response to emerging neurotechnologies. See NeuroRights Foundation, *Our Mission* (https://neurorightsfoundation.org/our-mission) accessed 16 June 2025.

protection against algorithmic bias as a further concern. This model gained international visibility and became a point of reference in both academic and policy debates.

A further step in the evolution of the academic understanding of neurorights came in 2023, when Sjors Ligthart, Marcello Ienca, and colleagues published a comprehensive mapping of neurorights in '*Minding Rights: Mapping Ethical and Legal Foundations of Neurorights'*[137], a comprehensive analysis that offered a structured overview of the ethical and legal foundations of mental rights in the age of neurotechnology. Rather than proposing a fixed taxonomy, the article emphasized a minimal set of core rights, especially mental privacy, cognitive liberty, and mental integrity, while acknowledging broader interpretative frameworks.

Not all scholars, however, are convinced that new rights are necessary. Nora Hertz, writing in 2022, questioned the proliferation of neurorights proposals, suggesting that many of the protections they aim to establish may already be covered under existing human rights instruments. She observed that the introduction of a specific right to mental self-determination 'would not necessarily lead to a higher level of protection. It has been argued that the scope of protection of the right to freedom of thought can be coherently interpreted in a broad way as protecting all mental processes from impermissible influence'[138]. Her critical perspective reminds us that the creation of new legal categories must be carefully justified, especially when existing norms may be reinterpreted or expanded to address emerging challenges. Altogether, the evolution of neurorights as an academic concept reflects a growing awareness of the ethical and legal implications of increasingly powerful brain-related technologies. From early philosophical appeals to mental autonomy to refined taxonomies of legal protections, scholars have laid the groundwork for what may become a defining field in the intersection of neuroscience, ethics, and human rights. Whether one supports the creation of entirely new rights or the reinterpretation of existing ones, the academic consensus is clear: the brain, as the seat of identity, consciousness, and freedom, requires a framework of protection that is as sophisticated and adaptive as the technologies that now seek to reach it.

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[137] Sjors Ligthart and others, 'Minding Rights: Mapping Ethical and Legal Foundations of "Neurorights"' (2023) 32 *Cambridge Quarterly of Healthcare Ethics* 461.

[138] Nora Hertz, 'Neurorights – Do We Need New Human Rights? A Reconsideration of the Right to Freedom of Thought' (2023) 16 *Neuroethics* 5, 12.

2.2 Overview of the potential rights involved

2.2.1 Literature perspectives on key rights involved

As noted in the previous chapter, the conceptual foundation of neurorights was laid by Marcello Ienca and Roberto Andorno in their influential 2017 publication *Towards new human rights in the age of neuroscience and neurotechnology*. Recognizing that neurotechnologies were no longer speculative but rapidly entering domains such as healthcare, defense, and personal enhancement, the authors argued that existing human rights frameworks were insufficient to address the new risks posed to the human mind. To remedy this, they proposed a set of four new human rights, referred to as neurorights, specifically designed to safeguard individual autonomy and mental integrity in the age of neuroscience. These four rights were: cognitive liberty, the right to freely choose whether or not to use neurotechnologies; mental privacy, the right to protect brain data from unauthorized access or misuse; mental integrity, the right to protection against non-consensual or harmful neural interference; and psychological continuity, the right to maintain a coherent and uninterrupted sense of personal identity over time. In their framework, these rights are not conceived as entirely new legal inventions, but rather as necessary updates and extensions of existing human rights principles in light of emerging technological challenges.

This four-part model, grounded in the principles of autonomy, dignity, and mental self-determination, has had a profound influence on the academic debate, prompting ethical, legal, and policy discussions across disciplines. However, it remains a normative proposal situated primarily within academic literature, rather than a codified legal standard.

In parallel with this scholarly work, a more activist and policy-oriented framework was developed by the NeuroRights Foundation, initially launched as the NeuroRights Initiative at Columbia University. This initiative proposes five neurorights: cognitive liberty, mental privacy, personal identity, free will, and fair access to mental augmentation. While there is clear conceptual overlap, particularly regarding cognitive liberty and mental privacy, the NeuroRights Foundation's model introduces two key distinctions. First, it separates free will (understood as decisional autonomy) from personal identity (as the subjective experience of self), whereas Ienca and Andorno treat psychological continuity as encompassing both. Second, it includes a positive right to fair access to cognitive enhancement, which is absent in Ienca and Andorno's rights-based framework.

These differences reflect distinct aims: Ienca and Andorno offer a normative-legal theory rooted in human rights philosophy, while the NeuroRights Foundation advances a politically actionable agenda aimed at legislative reform. In the following sections, particular attention will be given to the model proposed by Ienca and Andorno, as it was the first comprehensive framework introduced in the academic debate on neurorights. This choice is also motivated by the model's conceptual clarity, its influence on subsequent discussions, and its grounding in established principles of bioethics and human rights.

2.2.2 Cognitive liberty

Cognitive liberty stands as the foundational pillar of the neurorights framework articulated by Marcello Ienca and Roberto Andorno in their seminal 2017 article *Towards new human rights in the age of neuroscience and neurotechnology*. The authors, building on Bublitz's[139] analysis, define cognitive liberty as '(a) the right of individuals to use emerging neurotechnologies; (b) the protection of individuals from the coercive and unconsented use of such technologies'[140]. This dual formulation emphasizes both the freedom to enhance or modify cognitive functions and the right to mental self-determination against unwanted interference.

Cognitive liberty is conceptually linked to traditional human rights such as freedom of thought and freedom of conscience. However, Ienca and Andorno argue that these existing rights are insufficient in the face of neurotechnologies capable of decoding, influencing, or even manipulating thought processes. As neurotechnological tools move from clinical to consumer domains, ranging from brain-computer interfaces to neuromarketing, the risk of infringing on mental autonomy becomes increasingly

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[139] See Jan-Cristoph Bublitz, 'My Mind is Mine!? Cognitive Liberty as a Legal Concept' in Elisabeth Hildt and Andreas G Franke (eds), *Cognitive Enhancement: An Interdisciplinary Perspective* (Springer 2013) 233–64.

[140] Ienca and Andorno (n 133) 10.

tangible. The right to cognitive liberty, in this context, emerges as a necessary normative safeguard against both coercive and covert intrusions into one's mental domain.

In later work[141], cognitive liberty is reaffirmed as a core component of any legal framework aimed at protecting mental integrity. The authors emphasize its dual role: as a shield protecting individuals from external manipulation, and as a sword enabling them to access safe and voluntary neurotechnological interventions.

Furthermore, cognitive liberty also raises legal and philosophical challenges. For instance, the application of neurotechnologies in forensic or educational settings may pressure individuals to undergo neural monitoring or stimulation without meaningful consent. The criminal justice system, 'is increasingly incorporating predictive neurocognitive methodologies and machine learning algorithms, significantly influencing real-world forensic and judicial decision-making processes'[142] which raises serious concerns about the intrusion into individuals' mental privacy and decisional autonomy. Similarly, in educational contexts, some studies have pointed to:

> the ignorance of bad and undesirable effects of neurotechnology on human beings in the classrooms; the inconsideration of ethical issues based on human rights, brain rights, mental privacy, free will and personal identity; ... and the reduction of non-verbal communications in the interactions between the students and the teachers. [143]

In such cases, the absence of explicit legal recognition for cognitive liberty could result in ethically problematic practices under the guise of efficiency or security, particularly when technologies are implemented without fully addressing their implications for autonomy, consent, and human dignity.

2.2.3 Mental privacy

The right to mental privacy has emerged as a foundational element in the landscape of neurorights, addressing the need to protect individuals from unauthorized access to their

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[141] See Ligthart and others (n 137) 468.

[142] E García-López, C Nombela and E Demetrio Crespo, 'Editorial: Law and Neuroscience: Justice as a Challenge for Neurorights, Neurolaw, and Forensic Psychology' (2025) 16 *Frontiers in Psychology* 1615234, 2.

[143] Javad Alipoor and Hatef Pourrashidi, 'A Critical Study on the Researches about the Application of Neurotechnology in Education' (2024) *International Journal of Neuroscience* 7.

brain data and mental states. Building on the historical foundations of privacy theory, most famously articulated by Warren and Brandeis in 1890 as ‘the right to be let alone’[144], mental privacy introduces a new layer of protection adapted to the challenges posed by modern neurotechnologies.

This evolving notion of mental privacy compels a broader reflection on the scope of protections traditionally afforded to freedom of thought. Historically, safeguards have centered on the external dimension of thought, its verbal or behavioral expression, leaving the inner, formative stage largely unaddressed. Yet, the capacity of neurotechnologies to access neural patterns before any conscious articulation reveals a profound vulnerability: the origination of thought itself. Unlike expressed thought, which individuals can choose to reveal or withhold, the mental processes that precede expression unfold involuntarily and are entirely beyond deliberate control. Precisely because of this intrinsic lack of agency, the formative stage of thought demands the highest level of protection, as it constitutes the most intimate and unmediated space of individual selfhood, a space that must undoubtedly be protected under the principle of mental privacy.

Ienca and Andorno[145] identify mental privacy as one of the emerging rights necessary to safeguard individuals from the risks posed by neurotechnological tools capable of accessing neural activity. Rather than treating brain data as a mere subset of health or biometric information, they emphasize that such data can expose deeply intimate aspects of a person’s inner life. Existing privacy frameworks, they argue, are insufficient to protect against these novel risks. They define the right to mental privacy as one ‘which aims to protect any bit or set of brain information about an individual recorded by a neurodevice and shared across the digital ecosystem’[146].

While grounded in the broader right to privacy, enshrined in instruments like Article 12 of the Universal Declaration of Human Rights (UDHR)[147] and Article 8 of the European Convention on Human Rights (ECHR)[148], mental privacy represents a distinct legal and

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[144] Samuel D Warren and Louis D Brandeis, ‘The Right to Privacy’ (1890) 4(5) *Harvard Law Review* 193-220.

[145] Ienca and Andorno, (n 133) 15.

[146] ibid.

[147] Universal Declaration of Human Rights (UDHR) (adopted 10 December 1948 UNGA Res 217 A(III)) art 12: ‘No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks’.

[148] European Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR) art 8: ‘1. Everyone has the right to respect for his

ethical concern. Traditional privacy law was never designed to address data derived from brain activity, and thus fails to fully capture the risks posed by modern neuroimaging tools or brain-computer interfaces.

Nonetheless, as argued by Ligthart and colleagues[149], mental privacy draws implicit normative support from a set of existing human rights, namely, the rights to privacy (as noted before: UDHR art. 12 and ECHR art. 8), freedom of thought (UDHR art 18[150]), and freedom of expression (UDHR art 19[151] and ECHR art 10[152]). Each of these offers partial but significant protection for the mental domain. The right to privacy provides general safeguards against unlawful intrusion into personal life, which may be extended to include brain data. The right to freedom of thought, often treated as absolute in international law, protects individuals from coercive influence over their inner beliefs and ideations. Lastly, the right to freedom of expression not only guarantees the ability to communicate freely but also includes the right not to disclose one's thoughts. Together, these rights form a foundational basis for defending mental privacy, especially in light of emerging neurotechnologies capable of detecting and decoding mental content that individuals have neither expressed nor intended to share.

Another important aspect is connected with the very nature of this right: whether it is absolute or relative, as explicitly addressed in Ienca and Adorno's work[153]. Like most human rights, the right to privacy is generally considered relative: it can be restricted under specific conditions, such as the protection of public order or national security, as allowed by Article 8(2) ECHR. This raises the question: should the right to mental privacy

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private and family life, his home and his correspondence. 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.

[149] Ligthart and others (n 137) 470.

[150] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III)) art 18: 'Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance'.

[151] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III)) art 19: 'Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers'.

[152] European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR, as amended) art 10: '1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers'.

[153] Ienca and Andorno (n 133) 15.

follow the same logic, or should it be elevated to an absolute right, immune from exceptions?

Practical legal frameworks still treat privacy as a balancing right. In exceptional cases, such as investigations into serious crimes, intrusions into personal data may be justified. In this context, brain data is often compared to other forms of evidence, such as DNA or fingerprints. However, the analogy falters when brain scans are used not to obtain physical data, but to reconstruct intentions or memories, which arguably cross into the domain of self-incrimination.

In light of these unresolved tensions, national data protection authorities may play a decisive role. These independent bodies, traditionally focused on informational privacy, could be instrumental in defining how emerging neurotechnologies are regulated and in interpreting whether neural data qualifies for special legal treatment. Their expertise and autonomy position them as natural candidates to oversee future safeguards for mental privacy.

In sum, the right to mental privacy addresses a critical gap in current legal and ethical frameworks. As technology advances to decode and even predict mental content, this right must be articulated clearly and protected robustly, whether as a reinforced form of informational privacy or as a standalone, inviolable domain of the self.

2.2.4 Mental integrity

Among the growing concerns surrounding the development of neurotechnologies, the issue of mental integrity stands out as particularly urgent. As devices gain the ability not only to monitor but also to influence the brain's activity, the need to ensure that individuals retain sovereignty over their mental processes becomes critical. Mental integrity refers to the right to be protected from unauthorized interference with one's mental functions, including manipulation, disruption, or harm to one's thoughts, emotions, and decision-making capacities.

As neurotechnology advances, the human mind is becoming increasingly accessible. Techniques such as EEG, fMRI, and brain-computer interfaces now enable the decoding of neural activity related to intentions, preferences, and even political orientation. It has been observed that 'emerging neurotechnologies have the potential to allow access to at least some components of mental information'[154] with the result that the mind may 'no longer be such unassailable fortress'[155]. This erosion of mental autonomy raises profound concerns about how to safeguard individuals' inner lives.

Mental integrity is conceptually similar to bodily integrity, but it addresses the protection of the mental domain. As Ligthart et al. explain, 'the right to mental integrity, on a minimalist conception, would protect against certain forms of interference with one's mind'[156]. Such interference could include direct manipulation through brain stimulation or subtler forms of influence via neuromarketing and behavior prediction. With the rise of non-invasive brain stimulation technologies such as tDCS and TMS, the risk of unwanted cognitive modulation is growing. The same authors note that 'nonconsensual NIBS [Non-Invasive Brain Stimulation] could amount to a severe mental interference, and thus a serious violation of the right'[157].

From a normative standpoint, the right to mental integrity enjoys a relatively high degree of international legal recognition, as it is already enshrined in human rights instruments and offers a coherent framework centred on protection from harm[158]. This normative grounding reinforces its status as a foundational neuroright, particularly in the face of emerging neurotechnological threats that challenge individual autonomy and mental self-determination.

In light of these developments, mental integrity must be recognized not only as a theoretical construct but as a practical legal safeguard, essential for preserving individual autonomy in the age of neurotechnology. As the boundaries between thought and intervention grow increasingly blurred, the protection of the mental domain becomes a cornerstone for ensuring human dignity, freedom, and selfhood in digitally and neurologically mediated societies. Embedding this right within enforceable legal frameworks is no longer a speculative aspiration but a necessary step toward upholding fundamental rights in the face of unprecedented cognitive vulnerabilities

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[154] Ienca and Adorno (n 133) 1.

[155] ibid.

[156] Ligthart and others (n 137) 466.

[157] ibid.

[158] The legal entrenchment of mental integrity is discussed in detail by Ienca, who identifies two main interpretive models. One, supported by Ienca and Andorno, sees the right as protection against illicit or harmful interference with mental activity. The other, proposed by Lavazza, focuses on an individual's exclusive control over mental states and brain data. The first interpretation presents mental integrity as complementary to cognitive liberty and freedom of thought; the second treats it as a functional equivalent. See Marcello Ienca, 'On Neurorights' (2021) 15 *Frontiers in Human Neuroscience* 701258, 7.

2.2.5 Psychological continuity

Among the neurorights proposed in recent years to address the ethical and legal implications of neurotechnology, the right to psychological continuity stands out as a fundamental safeguard of personal identity. It ‘tends to preserve personal identity and the coherence of the individual’s behavior from unconsented modification by third parties. It protects the continuity across a person’s habitual thoughts, preferences, and choices by protecting the underlying neural functioning’[159].

In an era where devices are increasingly able not only to monitor but also to modulate brain activity, this right aims to protect individuals from disruptions that could undermine the integrity of their personality, memories, and sense of self.

Psychological continuity addresses a critical risk: that neurotechnological interventions, particularly those that are involuntary or insufficiently regulated, might sever the narrative thread of a person’s mental life. This thread is essential to our self-conception as the same person over time. Without it, one’s identity could be fragmented or overwritten. The concern is particularly pressing in relation to closed-loop devices, which, in the future, could ‘monitor the brain of an offender and intervene upon it in order to avert an angry outburst that might precipitate an offense’[160].

While such interventions may appear beneficial on the surface, they raise significant ethical issues when they alter emotional reactions, beliefs, or memories that are constitutive of one’s personality. In this sense, the growing use of neurotechnologies ‘will force a reconceptualization of certain human rights, or even the creation of new rights to protect people from potential harm’[161].

Psychological continuity is one of those rights, emerging in response to the novel and profound ways in which technology can affect the mind. Its normative foundation lies in the notion that continuity of identity is not just a metaphysical or psychological concept, but a legal and ethical interest worthy of protection, particularly when faced with powerful tools capable of modifying brain function directly.

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[159] Ienca and Andorno (n 133) 21.
[160] Ligthart and others (n 137) 462.
[161] Ienca and Andorno (n 133) 2.

Moreover, the right to psychological continuity implies that individuals should have the ability to control not just how their minds are influenced, but whether such influence is consistent with their own sense of self.

Especially in non-clinical settings such as criminal justice, education, or workplace environments, the imposition of neurotechnological influence could create discontinuities in memory or personality that effectively amount to a partial psychological replacement of the individual.

What distinguishes psychological continuity from related rights such as mental integrity is its focus on temporal persistence. While mental integrity guards against intrusions at any given moment, psychological continuity addresses the enduring coherence of a person's identity over time. In this sense, it protects not only against acute violations, but also against the cumulative effects of repeated or long-term neural interventions that may slowly erode or reconfigure the self.

2.3 Neurorights: new rights or extension of existing rights?

2.3.1 Arguments in favor of introducing new rights

In the previous chapters, the emerging field of neurotechnology and its implications for individual autonomy, privacy, and identity have been extensively discussed. Particular attention was paid to the conceptual foundation of neuro-rights and the critical need to protect neurodata in an increasingly digitized society. While this has built a strong case for the necessity of safeguarding the human mind, it is important to recognize that not all scholars and legal theorists agree that neurorights should be recognized as *new* fundamental rights. A significant portion of the debate revolves around whether existing human rights frameworks can adapt to meet neurotechnological challenges, or whether entirely new legal categories are required. The critiques of rights proliferation and the risks of fragmenting international law will be addressed in the following chapter. Here, the focus is exclusively on the position of those who advocate for the formal recognition of neuro-rights as novel, fundamental rights tailored to the neurological domain.

Central to this position is the unprecedented capability of neurotechnology to access and manipulate the human mind. The ability to decode thoughts, influence decisions, or implant artificial memories is not theoretical, it is rapidly becoming technologically viable. As recent literature has stressed, we are facing 'the real possibility of human thoughts being decoded or manipulated using technology'[162]. This reality marks a paradigm shift. While earlier technologies mediated behavior or communication, neurotechnology directly interfaces with cognition itself, demanding an equally direct legal response.

The unique nature of neurotechnologies, their capacity to penetrate, monitor, and even manipulate neural activity, has led a number of legal theorists and international institutions to argue for the creation of entirely new categories of fundamental rights. These are not simply extensions of existing rights to privacy or autonomy, but distinct legal constructs designed to protect what the UN Human Rights Council Advisory Committee refers to as 'mental and cognitive functions'[163] from intrusive interference. In its 2024 report, the Committee emphasizes that such technologies '[question] the very understanding of the foundational principles of human rights'[164], and that 'context-specific standards to protect against the non-consensual intrusion of third parties may be necessary'[165]. Similarly, the UN Human Rights Council Advisory Committee has observed that existing legal models developed for data protection and biotechnology are 'useful in addressing some of the new issues and conflicts posed by neurotechnology from the human rights perspective, but … some of the issues and conflicts are new and different from those previously addressed by the law'[166]. As a result, the Committee concludes that 'we should develop and include new rights and guarantees'[167]. Neurorights are

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[162] Rafael Yuste, Jared Genser and Stephanie Herrmann, 'It's Time for Neuro-Rights: New Human Rights for the Age of Neurotechnology' (2021) *Horizons* (Centre for International Relations and Sustainable Development) Issue 18 (Winter 2021) 155. https://www.cirsd.org/files/000/000/008/47/7dc9d3b6165ee497761b0abe69612108833b5cff.pdf accessed 20 July 2025.

[163] UN Human Rights Council Advisory Committee, *Impact, Opportunities and Challenges of Neurotechnology with Regard to the Promotion and Protection of All Human Rights* UN Doc A/HRC/57/61 (6 July 2024) https://undocs.org/en/A/HRC/57/61 accessed 20 July 2025, 2.

[164] ibid.

[165] ibid 5.

[166] UNESCO International Bioethics Committee, *Report of the International Bioethics Committee of UNESCO (IBC) on the Ethical Issues of Neurotechnology* SHS/BIO/IBC-28/2021/3 Rev (Paris, 15 December 2021).

[167] ibid.

increasingly seen as requiring independent legal recognition, signaling a shift toward a dedicated normative framework for the protection of the human mind.

Importantly, current international treaties are structurally and conceptually unprepared for these developments. While documents like the International Covenant on Civil and Political Rights (ICCPR) protect against arbitrary interferences with privacy and uphold freedom of thought[168], they were crafted in a pre-digital world. The tools and threats of today, and especially those of tomorrow, fall outside their conceptual horizon. As it has been argued, 'existing treaties cannot offer the robust and comprehensive human rights protection that a neurotechnological world requires'[169]. The absence of legal categories specific to brain data, mental integrity, and agency results in a normative vacuum at precisely the moment we need protections most.

This gap is further exacerbated by the rise of consumer-grade neurotechnologies. Devices marketed for entertainment, wellness, or productivity can now collect neural signals at scale, and do so in largely unregulated environments. In this context, 'consumer neurotechnology devices are unregulated and consumer brain data remain unprotected'[170]. The distinction between medical and non-medical applications, often used to determine the applicability of regulations, becomes increasingly untenable when the same technology can serve both diagnostic and commercial purposes.

In sum, the arguments in favor of recognizing neurorights as new fundamental rights stem not from abstract speculation, but from growing concerns about the concrete and unprecedented ways in which neurotechnologies interact with the human mind. From clinical experimentation to consumer applications, these technologies are reshaping the boundaries between internal thought and external influence. Supporters of this perspective argue that existing legal protections may no longer be adequate in addressing the specific challenges posed by this transformation. Whether this justifies the establishment of an entirely new category of rights remains an open question, one that demands careful consideration of both the conceptual and practical implications. The following chapter will explore the critical perspectives that question the necessity,

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[168] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, arts 17 and 18.

[169] Yuste (n 162).

[170] Sean Pauzauskie, Jared Genser and Rafael Yuste, 'Protecting Neural Data Privacy—First, Do No Harm' (2025) 82(3) *JAMA Neurology* 212 https://doi.org/10.1001/jamaneurol.2024.4070 accessed 21 July 2025.

efficacy, or desirability of introducing new legal frameworks for neurotechnological governance.

2.3.2 Reworking existing fundamental rights

While a growing number of scholars and institutions advocate for the creation of novel “neurorights” in response to emerging neurotechnologies, several legal and ethical experts have cautioned against this approach. These authors argue that existing fundamental rights, if interpreted and applied dynamically, offer sufficient protection against the challenges posed by modern neurotechnologies.

A core concern raised by scholars opposing the creation of novel human rights for neurotechnology is the risk of rights inflation, whereby the overproduction of human rights claims diminishes the normative force of the entire framework. As Ienca explicitly warns, ‘the unjustified proliferation of new rights should be avoided. The unjustified proliferation of human rights is problematic because it may spread skepticism about all human rights, as it dilutes them to mere moral desiderata or purely rhetorical claims’[171]. He further elaborates that such proliferation ‘distracts from the central goal of human rights instruments, which is to protect a set of truly fundamental human interests, and not everything that would be desirable or advantageous in an ideal world’[172]. This critical stance is grounded in the belief that the moral and legal weight of human rights must be preserved, and that labeling every emerging ethical concern as a “right” risks trivializing the concept itself.

Building on this concern, Muñoz and Marinaro[173] assess the legitimacy of introducing neurorights by applying a classical legal-dogmatic framework, which considers whether new rights are justified by contradiction with existing norms, redundancy, inefficiency, or legal gaps. Their conclusion is that none of these conditions meaningfully support the case for new legal categories. Rather than identifying conflict or overlap with current human rights provisions, they suggest that existing frameworks are largely harmonious

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[171] Marcello Ienca, 'On Neurorights' (2021) 15 *Frontiers in Human Neuroscience* 701258, 9.

[172] ibid.

[173] José M Muñoz and José Ángel Marinaro, ‘Neurorights as Reconceptualized Human Rights’ (2023) 5 *Frontiers in Political Science*, Politics of Technology https://doi.org/10.3389/fpos.2023.1322922 accessed 21 July 2025.

with the objectives neurorights seek to fulfill. As an illustrative example, they consider the claim that current rights are inefficient at protecting individuals from neurotechnological risks. Yet, they argue that neurorights 'could complement but never replace the incalculable value of present human rights'[174] suggesting that the inefficiency lies not in the structure of existing rights, but in their implementation or interpretation. Even in cases where apparent legal voids exist, such as in regulating emerging technologies that impact cognitive liberty or mental privacy, the authors propose that these can be addressed by refining and expanding current doctrines.

A further critical dimension of the debate on neurorights concerns the conceptual and normative ambiguity that often surrounds their definition. Scholars such as Francesco Cirillo have warned that the discourse on cognitive liberty and related neuro-rights risks 'belonging more to the realm of problems than to that of solutions'[175]. This position reflects a broader unease about the proliferation of loosely defined rights categories, which may generate legal uncertainty rather than meaningful protection. Rather than strengthening the legal architecture, such initiatives might contribute to its fragmentation, especially when they are not grounded in clear doctrinal foundations. Echoing this skepticism, Oreste Pollicino has argued that the juridical basis for protecting mental integrity and brain data may already be embedded within existing constitutional charters, asserting that 'the foundations of neurorights may already be (almost prophetically) present in existing Charters'[176]. This view underscores the intrinsic flexibility of constitutional systems, which are often structured to protect general legal categories capable of embracing new and complex juridical situations such as those posed by neurotechnologies; in fact, the intrinsic flexibility of every constitution, 'concerns the ability of the prescriptive framework to adapt to the specificities of new rights, including them within the protection traditionally afforded to established ones'[177]. In this sense, constitutional frameworks are not static, but dynamic instruments that can accommodate emerging rights without requiring their formal reinvention.

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[174] ibid 3.

[175] Francesco Cirillo, 'Neurodiritti: ambiguità della "libertà cognitiva" e prospettive di tutela' (2023) II *Consulta Online* 668 (author's translation).

[176] Oreste Pollicino, 'Costituzionalismo, privacy e neurodiritti' (2021) 2 *MediaLaws – Rivista di diritto dei media* 12 (author's translation).

[177] Giovanna De Minico, 'Nuova tecnica per nuove diseguaglianze. Case law: Disciplina Telecomunicazioni, Digital Services Act e Neurodiritti' (2024) 6 *Federalismi.it* 5 (author's translation).

These observations suggest that, instead of inventing new rights from scratch, a more effective strategy could involve uncovering and adapting the potential of current human rights frameworks, using established categories to respond to novel neurotechnological risks.

This approach, relying on the evolution of interpretation rather than the invention of new categories, is echoed by other prominent scholars. Nora Hertz, for instance, directly challenges the necessity of a new right to mental self-determination by asserting that the existing right to freedom of thought, as articulated in Article 9 of the European Convention on Human Rights and Article 18 of the International Covenant on Civil and Political Rights, already offers a strong normative basis for regulating the use of neurotechnologies. In her words, 'the right to freedom of thought can be coherently interpreted as providing comprehensive protection of mental processes and brain data'[178], and she concludes that 'an evolving interpretation of the right to freedom of thought is more convincing than introducing a new human right to mental self-determination'[179].

This idea is reinforced within the European legal context: 'a right to mental privacy could be derived from, or at least developed within the jurisprudence of the European Court of Human Rights"[180] rejecting the necessity of introducing "an additional fundamental right to protect against (forensic) brain-reading'[181]. The view advanced is that 'drawing out such implications is a commonplace legal activity and does not require novel rights'[182] indicating a clear preference for juridical continuity and interpretive flexibility over normative rupture.

The same critical tone is present in the work of Jan Christoph Bublitz, who strongly contests the legitimacy and utility of the proposed neurorights. Specifically, he directs his critique at the set of rights advocated by the Neurorights Initiative[183]. Bublitz categorically states that 'the proposed rights, as individuals and a class, should not be adopted and lobbying on their behalf should stop'[184]. His reasoning stems from the

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[178] Nora Hertz, 'Neurorights – Do We Need New Human Rights? A Reconsideration of the Right to Freedom of Thought' (2023) 16 *Neuroethics* 5, 4.

[179] ibid.

[180] Niels Ligthart, 'Forensic Brain-Reading and Mental Privacy in European Human Rights Law' (2022) 5 *Ethics and Neurotechnology* 187, 2.

[181] ibid.

[182] ibid 3.

[183] See n 136.

[184] Jan Christoph Bublitz, 'Novel Neurorights: From Nonsense to Substance' (2022) 16 *Neuroethics* 15.

observation that the push for new rights bypasses the foundational legal analysis typically required in the development of human rights, which always involves the examination of the existing gaps in the current legal system, in this sense, 'the proposal seems to skip this step by assuming that current law is inadequate'[185], he writes, pointing to a lack of rigorous doctrinal justification. He further notes that 'none of the proposed rights passes quality control according to the Alston criteria'[186](187) and argues that they 'offer solutions for problems which may not exist in the alleged way; they seek recognition as human rights without recognizing human rights law'[188].

Finally, Stephen Rainey brings a philosophical and jurisprudential perspective to the critique. Analyzing the concept of rights through Hohfeld's framework[189], he concludes that the issues neurorights aim to address (mental integrity and cognitive liberty) do not warrant the creation of new legal rights but should rather be managed through 'careful use of existing legislation on data protection'[190]. Rainey argues that 'protections for mental integrity and cognitive liberty are best accounted for in terms of familiar and established rational and discursive norms'[191], suggesting that these domains are governed more appropriately by ethical reasoning and regulatory refinement than by the constitutionalization of new rights. In his words, 'calls for neurorights propose an overcomplicated approach'[192] and he questions whether the language of "rights" is even appropriate in this context, since "rights-talk" often obscures more than it clarifies.

In conclusion, the argument against the creation of new neurorights is not a rejection of the challenges posed by neurotechnology, but a principled stance on how best to address them. The legal, ethical, and philosophical analysis across these contributions converge on a common theme: the tools already exist within the human rights system to regulate the evolving impact of brain-related technologies. The task is not to multiply rights

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[185] ibid 6.

[186] ibid 12.

[187] The "Alston criteria" refer to standards developed by Philip Alston to evaluate the legitimacy of new human rights, including tests of necessity, precision, and consistency.

[188] Bublitz, (n 184) 12.

[189] Hohfeld's framework categorises legal relations into distinct analytical positions—rights, duties, privileges, no-rights, powers, liabilities, immunities, and disabilities—to clarify the precise structure of legal entitlements. Referencing this model allows for a nuanced assessment of whether proposed neurorights constitute genuine rights or merely liberties that do not impose correlative duties on others.

[190] Stephen Rainey, 'Neurorights as Hohfeldian Privileges' (2023) 16 *Neuroethics* 9.

[191] ibid.

[192] ibid.

without necessity, but to revisit and reinforce those already in place, through reconceptualization, interpretation, and adaptation.

2.4 International regulations on neurorights

2.4.1 OECD recommendations for responsible innovation

The OECD's *Recommendation on Responsible Innovation in Neurotechnology*, adopted by the OECD Council in December 2019, constitutes the first international legal instrument specifically dedicated to the governance of neurotechnologies. It is a non-binding "soft law" framework, but with high persuasive authority, offering a common set of values, priorities, and policy guidelines to member states.

The document is structured around nine high-level principles[193]: each one is accompanied by policy suggestions, often balancing technical innovation with ethical restraint.

The Recommendation calls on governments and relevant actors to 'show due regard for human rights and societal values, especially privacy, cognitive liberty, and autonomy of individuals'[194]. It further encourages policies that 'protect personal brain data from being used to discriminate against or to inappropriately exclude certain persons or populations'[195], and explicitly warns against 'manipulation of brain states'[196] or 'neurotechnology innovation that seeks to affect freedom and self-determination'[197]. These provisions reflect the growing concern that neurotechnology must not only ensure data security and physical safety, but also protect mental integrity, what is increasingly referred to as cognitive liberty. This concept refers to the right of individuals to maintain sovereignty over their mental processes, free from coercive technological intrusion, whether through direct stimulation or indirect profiling, such as neuro-targeted advertising or AI-based inference of traits.

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[193] The nine principles include: promoting innovation, ensuring safety, inclusivity, scientific collaboration, public deliberation, oversight capacity, protection of brain data, trust across sectors, and monitoring misuse. See: Organisation for Economic Co-operation and Development, *Recommendation of the Council on Responsible Innovation in Neurotechnology* OECD/LEGAL/0457 (11 December 2019) https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457 accessed 19 June 2025.

[194] ibid Principle 1(d).

[195] ibid Principle 7(d).

[196] ibid Principle 9(c).

[197] ibid Principle 1(e).

While the document does not prescribe strict regulatory models, it acknowledges that ‘there may be diverse ways of putting responsible innovation into practice’[198] adding that ‘such diversity creates an opportunity for learning’[199]. This leaves room for institutional pluralism while still promoting convergence around shared ethical principles. The Recommendation also calls for interdisciplinary dialogue among scientists, industry stakeholders, ethicists, and citizens[200]. In this sense, it operates not only as a policy guide but also as a platform for fostering a global conversation on neuroethics, governance, and responsibility.

These principles were not merely aspirational. The OECD had already acknowledged, prior to the formal adoption of the Recommendation, the concrete difficulties surrounding their implementation, particularly within private-sector contexts marked by fast-paced innovation and regulatory ambiguity. As reported in the 2019 Working Paper summarising the Shanghai Expert Workshop[201], participants noted that ‘a highly heterogeneous international landscape of innovation practices, regulation of nascent markets, and de-facto standards … creates uncertainty among public and private sector actors’[202]. Moreover, it was observed that ethical frameworks and responsibility tools ‘must be carefully tailored to the needs and constraints of the private sector’[203]. This reflects a fundamental tension identified during the workshop: while neurotechnology enterprises are enthusiastic about innovation, they often operate in normative grey zones, where ethical aspirations are strong but institutional and legal safeguards remain fragmented and underdeveloped.

To address this, the OECD developed a more operational document: the *Neurotechnology Policy Toolkit for Responsible Innovation*, published in April 2024. It is ‘based on its own

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[198] ibid Preamble (‘Recognising that given the different cultural understandings of the brain and mind…’).

[199] ibid.

[200] ibid Principle 5.

[201] The Shanghai Expert Workshop was a high-level meeting organised by the OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT), held in Shanghai in October 2018. It brought together policymakers, ethicists, scientists, and industry leaders to discuss the governance challenges of emerging neurotechnologies and helped shape the subsequent OECD Recommendation.

[202] Organisation for Economic Co-operation and Development, *Responsible Innovation in Neurotechnology Enterprises: Proceedings from the Shanghai Workshop* (OECD Science, Technology and Industry Working Papers No 2019/06, 2019) 5.

[203] ibid 22.

refined principles, from nine to five, to offer further specifics and examples across thematic implementation goals for neurotechnology innovation'[204].

This shift from broad ethical ideals to concrete governance tools has been both welcomed and scrutinized by scholars. As the OECD notes, '"anticipatory technology governance" encourages a shift in how we imagine the challenge of governance from the management of technological risks to "getting ahead" of technology developments'[205]. This means that ethical frameworks must not only be implemented but integrated early and flexibly in the development cycle, especially as neurotechnologies and other emerging tools move into sensitive societal domains. As the framework emphasizes, 'embedding values in the innovation process requires ... integrating values through diverse means in different phases of the innovation cycle'[206], making anticipation a central component of ethical governance in rapidly evolving contexts.

In sum, the OECD's work on neurotechnology governance reflects a maturing global effort to balance innovation with ethical responsibility. By moving from high-level principles to more operational guidance, the OECD reinforces the idea that responsible neurotechnology requires both shared values and concrete mechanisms for implementation. As the field continues to evolve, this dual approach, anchored in anticipatory governance and cognitive liberty, will be essential to ensuring that neurotechnological progress serves human dignity and democratic ideals.

2.4.2. UNESCO initiatives on neurotechnology regulation

UNESCO is leading an unprecedented global effort to shape binding ethical standards for the development and use of neurotechnology.

Following a mandate from the General Conference in November 2023, Director-General Audrey Azoulay appointed a geographically balanced Ad Hoc Expert Group (AHEG)[207] of twenty-four specialists that convened in Paris in April 2024 to draft the text, refined it at a second session in August, and circulated a first draft to all 194 Member States in

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[204] Judy Illes and others, 'Principles and Priorities for Responsible Innovation in Neurotechnology for Canada' (2025) 52 *Canadian Journal of Neurological Sciences* 559, 561.

[205] Organisation for Economic Co-operation and Development, *Framework for Anticipatory Governance of Emerging Technologies* (OECD Publishing 2024) 10.

[206] ibid 14.

[207] See https://www.unesco.org/en/ethics-neurotech/recommendation/expert-group.

September 2024. The instrument is scheduled for adoption in November 2025, concluding a two-year process initiated by UNESCO to define a global normative framework grounded in shared ethical principles and human rights.

At the heart of the draft is a clear warning that neurotechnology is no ordinary suite of tools. The Preamble states that it 'raises fundamental ethical issues for instance regarding self-determination, privacy, personal identity, freedom of thought, risk of discrimination, inequality and challenges to democracy'[208], and insists that 'justice, trust and fairness must be upheld so that no country and no one should be left behind'[209].

That rights-based framing is deepened in the section on mental privacy. Neural and cognitive-biometric data, the draft notes, 'can be processed to infer mental states'[210], creating unprecedented possibilities for profiling, manipulation and surveillance. Accordingly, the Recommendation treats such data as inherently sensitive and calls on States to introduce affirmative-consent rules, data-minimisation duties and explicit bans on non-consensual extraction or commercialization, especially in workplaces, education, marketing or political persuasion.

The Recommendation grounds its ethical approach in a set of core principles that articulate the values guiding the responsible development and use of neurotechnology. These principles serve as the normative foundation of the instrument, linking the protection of human dignity and individual rights to broader concerns of justice, accountability, and global equity. Importantly, they are not treated as abstract ideals but are tied to concrete policy obligations. States are called upon to establish mechanisms for ethical impact assessment prior to market deployment, to ensure monitoring throughout the technology's lifecycle, and to implement robust cybersecurity and data protection measures. The draft also urges governments to prohibit coercive or manipulative uses of neurotechnology, such as 'non-consensual interrogation in law enforcement, criminal and civil justice, development or deployment of neuroweapons, attempts at "moral enhancement" without consent, social control'[211] among others. In addition, it recommends that private sector actors be subject to binding requirements for human rights

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[208] UNESCO, *First Draft of a Recommendation on the Ethics of Neurotechnology (revised version): Working Document as of 27 August 2024* (SHS/BIO/AHEG-Neuro-2/2024/1, 2024) https://unesdoc.unesco.org/ark:/48223/pf0000387344 accessed 22 July 2025.

[209] ibid.

[210] ibid section 1.2 para 17.

[211] ibid section 4.1 para 70.

due diligence and risk management across their operations. Through this operational framing, the Recommendation seeks to embed ethical foresight into both public regulation and commercial innovation.

By recommending that States entrench these rights in domestic law, UNESCO seeks to ensure that any future enhancement or direct-to-consumer brain-monitoring devices remain subordinate to personal autonomy. The same logic informs the text's intellectual-property clause, which rules out proprietary claims over raw neural data, reserving protection only for genuinely creative compilations 'that meet strict, clearly defined criteria'[212].

The Recommendation does not stop at individual safeguards. It frames ethical governance as a participatory democratic task, urging States to develop an 'inclusive, and respectful dialogue between developers, users, and the broader public'[213]. That demand for inclusive deliberation is backed by provisions on global solidarity: Member States are asked to build capacities in low- and middle-income countries, support open-science repositories and align policies to avoid technology-driven inequities. Environmental sustainability also appears in the operational sections, with calls to reduce the data-centre footprint of large-scale brain-data processing and to recycle hardware responsibly.

Taken together, the draft Recommendation amounts to an anticipatory form of governance. It recognises the convergence of brain–computer interfaces, AI-assisted decoding and extended-reality headsets, and tries to set guard-rails before commercial adoption becomes ubiquitous. Its success will depend on whether Member States translate its principles into concrete domestic legislation and whether industry actors accept rigorous life-cycle oversight. Yet even in draft form, the Recommendation already signals a new normative horizon: one in which the protection of the human mind is treated as a global public good, inseparable from dignity, equality and democratic agency.

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[212] ibid section 4.2 para 88.

[213] ibid section 4.3 para 96.

2.5 Comparison between European and non-European models

2.5.1 European regulatory models

Given the ethical, legal, and societal implications raised by the use of neurodata, European institutions have not yet adopted a dedicated legal framework specifically targeting these technologies. However, the European Union has addressed many of the challenges posed by neurotechnologies through a constellation of existing and emerging legislative instruments. These instruments, though general in scope, reflect a growing commitment to safeguarding fundamental rights while promoting responsible technological development.

As already examined in section 1.4, a central pillar of the European approach to data protection is the General Data Protection Regulation (GDPR), adopted as Regulation (EU) 2016/679. This comprehensive framework establishes stringent requirements for the processing of personal data within the EU. Particularly relevant for neurotechnologies is Article 9, which prohibits, in principle, the processing of 'special categories of personal data'[214] including data concerning health and biometric data, unless specific conditions are met. Given that neurodata can reveal intimate information about an individual's cognitive state, emotional responses, and even political or religious beliefs, it arguably falls within these protected categories. As the GDPR states, 'processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or … data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited'[215]. The regulation does allow exceptions, such as when the data subject gives explicit consent[216] or when processing is necessary for reasons of public interest in the area of public health[217], but these are narrowly construed. Consequently, developers and researchers working with neurotechnological systems must implement rigorous safeguards to ensure compliance.

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[214] 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 (General Data Protection Regulation) [2016] OJ L119/1, art 9.

[215] ibid, art 9(1).

[216] ibid, art 9(2a).

[217] ibid, art 9(2i).

In parallel, the Medical Device Regulation (MDR), Regulation (EU) 2017/745, provides a complementary layer of oversight for neurotechnologies that are intended for medical purposes.

The MDR expands the definition of medical devices to include software and hardware used for therapeutic or diagnostic functions, which encompasses a wide array of neurotechnological tools. As defined in Article 2(1), a 'medical device' includes 'software … intended by the manufacturer to be used, alone or in combination, for human beings for one or more … medical purposes'[218]. Notably, devices that interact directly with the nervous system or monitor brain activity fall under the stricter classification rules due to their invasive nature and potential risks. According to Rule 8 of Annex VIII (MDR), implantable devices that 'are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system … are classified as class III'[219]; this classification corresponds to the highest risk category under the MDR, reserved for devices that pose a significant potential impact on patient health and safety.

The MDR mandates robust clinical evaluation, post-market surveillance, and conformity assessment procedures, emphasizing the need for safety, performance, and transparency.

In addition to sector-specific regulations such as the GDPR and the MDR, the European Union has established a comprehensive legal framework for artificial intelligence through the Artificial Intelligence Act (Regulation (EU) 2024/1689), formally adopted in June 2024.

Although the European Union's Artificial Intelligence Act (AI Act) does not explicitly mention neurotechnologies or neurodata, its principles and classification system provide clear indications of how such technologies would be regulated.

The AI Act establishes four levels of risk for AI systems: unacceptable risk, high risk, limited risk, and minimal risk. Of particular relevance to neurotechnologies is the first one.

Under Article 5, AI systems that pose an unacceptable risk are prohibited. These include systems that deploy subliminal or manipulative techniques designed to significantly

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[218] 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 [2017] OJ L117/1, art 2(1).

[219] ibid Annex VIII, Rule 8.

distort behaviour.[220]. Given that some neurotechnologies can directly influence neural activity and decision-making, potentially without the individual's full awareness, such tools could fall under these bans if used to manipulate behavior in a subliminal or deceptive way.

Moreover, AI used to infer emotions is also restricted. The Act bans systems with the scope of 'evaluation or classification of natural persons or groups of persons over a certain period of time based on their social behaviour or known, inferred or predicted personal or personality characteristic'[221]. Neurotechnologies designed to read emotional states, particularly in professional or educational contexts, could be seen as violating this clause, especially when using neurodata to derive such inferences.

The regulation also prohibits biometric categorization systems that deduce sensitive attributes such as 'race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation'[222]. If neurodata are used to infer or categorize such traits, the technology would clearly breach this provision.

Fundamentally, these regulatory mechanisms are anchored in the broader principles laid out in the Charter of Fundamental Rights of the European Union, which provides the normative foundation for EU law. Several articles are especially pertinent in the neurotechnological context. Article 1 establishes the right to human dignity, while Article 3 protects the right to integrity of the person, including respect for physical and mental integrity 'in the fields of medicine and biology'[223]. In addition, Articles 6, 7, and 8 safeguard liberty, privacy, and data protection, respectively. The invasive or influencing potential of neurotechnologies brings these rights into sharp focus. For example, the use of brain-monitoring tools in the workplace or courtroom could infringe upon mental privacy and the presumption of innocence, while cognitive enhancement devices may challenge notions of autonomy and equality. The Charter thus plays a critical role in guiding how EU legislation and policy frameworks are interpreted and applied in the neurodomain.

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[220] Regulation (EU) 2024/1183 of the European Parliament and of the Council of 13 March 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] OJ L202/1, art 5(1)(a).

[221] ibid Article 5 (1) (c).

[222] ibid Article 5 (1) (g)

[223] Charter of Fundamental Rights of the European Union [2012] OJ C 326/391, art 3(2).

In summary, the European regulatory approach to neurotechnologies is defined by a multi-instrumental strategy that integrates data protection, medical safety, artificial intelligence governance, and fundamental rights. While challenges remain in interpreting and enforcing these regulations in the face of rapid technological change, the EU has laid a robust groundwork that prioritizes individual dignity and ethical responsibility. As neurotechnology continues to evolve, the interplay between these legal sources will likely shape not only the legality of emerging innovations but also the societal values embedded within them.

2.5.2 Regulations in the United States and Latin America

Within the American legal framework, neural data protection is currently emerging through state-level statutes in California and Colorado, in the absence of a coordinated federal regime. These legislative initiatives mark important experimental steps in addressing the risks posed by neurotechnology to cognitive privacy.

In May 2024, California approved Senate Bill 1223, amending Civil Code Section 1798.140. It defines neural data as 'information that is generated by measuring the activity of a consumer's central or peripheral nervous system, and that is not inferred from nonneural information'[224] and classifying it as sensitive personal information. As such, it falls under the California Consumer Privacy Act (CCPA), requiring that businesses collecting neural data disclose the types collected, limit their use to disclosed purposes, and allow individuals to access and delete such information.

By including neural data within the statutory definition of sensitive personal information the law ensures that businesses collecting such data are subject to heightened obligations under the CCPA. Specifically, it entitles consumers to direct a business 'to limit its use of the consumers sensitive personal information to that use which is necessary to perform the services or provide the goods reasonably expected by an average consumer'[225] and to request the deletion or non-disclosure of such data. The inclusion of neural data aligns it with other sensitive categories such as biometric information and geolocation, reflecting

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[224] California Senate Bill 1223, *An Act to Amend Section 1798.140 of the Civil Code, Relating to Personal Information*(2024) https://legiscan.com/CA/text/SB1223/id/3023101 accessed 21 June 2025.

[225] ibid.

an intent to preemptively regulate forms of cognitive surveillance before they become ubiquitous in commercial practice.

Although the statute does not provide detailed regulatory mechanisms specific to neurotechnology, its definitional breadth allows it to apply across a range of contexts in which brain data may be processed, including wellness, consumer technology, and digital interfaces. The Legislature explicitly declares that these amendments 'further the purposes and intent of the California Privacy Rights Act of 202'[226] signaling the integration of neural data concerns into the broader architecture of Californian privacy law.

In contrast to California's comprehensive and cross-sectoral approach, Colorado's House Bill 24-1058, signed into law in April 2024, adopts a more targeted framework focused primarily on consumer-grade neurotechnologies. The statute amends the Colorado Privacy Act by adding 'biological data'[227] and 'neural data'[228] to the definition of sensitive data. It defines neural data as: 'information that is generated by the measurement of the activity of an individual's central or peripheral nervous systems and that can be processed by or with the assistance of a device'[229].

This formulation clearly encompasses non-invasive brain-computer interfaces, EEG headsets, and similar consumer-directed tools.

An additional relevant aspect concerns the recognition of the issues related to the granting of consent. Notably, the law itself acknowledges the inherent limits of user awareness when it comes to neural data collection, stating that:

> the collection of neural data always involves involuntary disclosure of information. Even if individuals consent to the collection and processing of their data for a narrow use, they are unlikely to be fully aware of the content or quantity of information they are sharing. [230]

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[226] ibid.

[227] Colorado House Bill 24-1058, An Act concerning the Privacy of Biological Data, and, in Connection Therewith, Amending the Colorado Privacy Act (2024) https://leg.colorado.gov/sites/default/files/documents/2024A/bills/2024a_1058_enr.pdf accessed 21 June 2025.

[228] ibid.

[229] Ibid, Section 1 (4) (b).

[230] Ibid, Section 1 (2) (f).

Although the new legal source introduces important privacy protections for neural data, the law leaves several critical issues unresolved. A key concern lies in the ambiguity of definitions. The statute defines neural data and biological data in ways that are ‘vague and ambiguous’[231]; in this sense the ‘law's definition of "neural data" may only cover raw neural data and not inferences obtained from processing such neural data’[232].

Furthermore, while the law acknowledges the complexity of informed consent, ‘the language in the preamble is nonbinding’[233], offering no operational standard to ensure such consent is genuinely informed in the neurodata context.

These two models, California’s broad and systemically embedded approach and Colorado’s targeted consumer protections, offer complementary visions. Both reflect a growing awareness that the commercialization of neural interfaces poses not only technical or economic questions, but fundamental legal and ethical ones.

In contrast to the more cautious and fragmented regulatory approach seen in the United States, Chile has taken a bold and centralized stance by becoming the first country in the world to enshrine neurorights directly into its constitutional framework.

This legal innovation aims to address the ethical and legal challenges posed by rapidly developing neurotechnologies, especially those capable of accessing or modifying brain activity. The 2021 constitutional reform states:

> Scientific and technological development shall be at the service of people and shall be carried out with respect for life and physical and mental integrity. The law shall regulate the requirements, conditions, and restrictions for its use on individuals, and must especially safeguard brain activity, as well as the information derived from it.[234]

Despite its visionary tone, the Chilean reform has been widely criticized for its conceptual vagueness and lack of legal precision. One key concern is that the law may unintentionally

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[231] Alston & Bird, *Key Issues Raised by Colorado’s Brain Data Privacy Bill* (30 April 2024) https://www.alston.com/en/insights/publications/2024/04/key-issues-raised-by-colorado accessed 21 June 2025.

[232] ibid.

[233] ibid.

[234] *Constitución Política de la República de Chile* [1980] art 19(1), as amended by Ley Núm 21.383 (2021) (author’s translation).

restrict beneficial research and treatments. Some argue that the current Chilean framework is ‘mono-valent’[235], focused exclusively on negative rights (i.e., protections from interference), without considering positive rights that support cognitive rehabilitation or medical use of neurotechnologies; also warning that such an approach could inadvertently conflict with established international human rights instruments, including the UN Convention on the Rights of Persons with Disabilities[236].

Another debated issue concerns the uncertain legal status of pharmacological cognitive enhancers within Chile’s neurorights framework. The proposed definition of neurotechnologies does not clarify whether such substances are included in the scope of regulation. This ambiguity has drawn criticism, as to whether the new legal initiative addresses ‘the inclusion (or not) of pharmacological neuroenhancers in the definition of the neurotechnologies it will regulate (and if included, how to deal with equitable access to this type of enhancement)’[237]. The absence of a clear stance appears to reflect the assumption ‘that the practice of neuroenhancement does not exist in Chile’[238] an assumption that risks leaving significant regulatory gaps unaddressed.

The initiative has also sparked debate within the broader Latin American context. While some countries (like Mexico, Argentina, and Colombia)[239], have shown growing academic interest in neurolaw, their contributions remain largely theoretical and are slowly moving toward concrete policy implementation. As noted, Latin America still lacks ‘its own research agenda for problems that may be specific to Latin America’[240] such as violence and poverty’s impact on cognition.

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[235] Joseph J Fins, 'The Unintended Consequences of Chile’s Neurorights Constitutional Reform: Moving Beyond Negative Rights to Capabilities' (2022) 15 *Neuroethics* 26, 2

[236] Fins observes that a neurorights framework focused solely on negative protections may inadvertently limit access to neurotechnologies essential for cognitive rehabilitation, thereby conflicting with the aims of the CRPD, which promotes inclusion and flourishing for persons with disabilities. See Fins (n 235); UN Convention on the Rights of Persons with Disabilities (adopted 13 December 2006, entered into force 3 May 2008) 2515 UNTS 3 (CRPD).

[237] María Ignacia Cornejo-Plaza and Catalina Saracini, 'On Pharmacological Neuroenhancement as Part of the New Neurorights’ Pioneering Legislation in Chile: A Perspective' (2023) 14 *Frontiers in Psychology* 1177720.

[238] ibid.

[239] For a broader overview of the emergence of neurorights across Latin America, see Future of Privacy Forum, ‘Privacy and the Rise of Neurorights in Latin America’ (FPF, 9 September 2021) https://fpf.org/blog/privacy-and-the-rise-of-neurorights-in-latin-america/ accessed 22 July 2025.

[240] Eric García-López, Ezequiel Mercurio, Alicia Nijdam-Jones, Luz Anyela Morales and Barry Rosenfeld, ‘Neurolaw in Latin America: Current Status and Challenges’ (2019) 18(1) *International Journal of Forensic Mental Health* 71.

In conclusion, a clear divergence emerges between the regulatory strategies adopted by the United States and Latin America. In the U.S., neural data protection is advancing through state-level, sector-specific statutes, with an operational focus on privacy, consent, and transparency in the commercial use of neurotechnologies. In contrast, Latin American efforts (most notably in Chile) are characterized by a strong constitutional and declarative orientation, aiming to enshrine fundamental rights related to mental integrity and brain activity. However, while the U.S. model, though fragmented, offers greater technical and practical clarity, Latin American initiatives, despite their ethical and symbolic ambition, have been criticized for conceptual vagueness and a lack of enforceable legal mechanisms. In both contexts, a persistent tension remains between protection and innovation, and between the affirmation of rights and their concrete implementation.

Chapter 3: Neurotechnology and Neuromarketing

3.1 Introduction to neuromarketing

3.1.1 Origins and main objectives of neuromarketing

Neuromarketing emerged in the early 2000s as an interdisciplinary field combining neuroscience, psychology, and marketing to investigate the unconscious processes driving consumer behavior. Its conceptual roots lie in the pioneering work of Daniel Kahneman and Amos Tversky, who, through a series of influential studies from the 1970s onward, demonstrated that human decision-making systematically deviates from rationality in predictable ways. In explaining these findings, they observed that 'choices among risky prospects exhibit several pervasive effects that are inconsistent with the basic tenets of utility theory'[241], revealing that people evaluate outcomes based on perceived gains and losses relative to a reference point, which leads to systematic biases like loss aversion and framing effects.

These insights challenged the traditional economic assumption of the fully rational consumer and laid the foundation for behavioral economics, inspiring marketers and neuroscientists to explore how real choices are made and highlighting the roles of emotion, habits, and automatic responses. Kahneman later summarized these findings arguing that 'most impressions and thoughts arise in your conscious experience without your knowing how they got there'[242], a statement that encapsulates the core idea that rapid, intuitive processes outside conscious awareness guide many consumer decisions.

The term neuromarketing was formally introduced in 2002 by Ale Smidts, who described his research as 'continuously searching for new methods that can enhance our understanding of decision-making processes'[243], emphasizing the importance 'to look at

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[241] Daniel Kahneman and Amos Tversky, 'Prospect Theory: An Analysis of Decision under Risk' (1979) 47(2) *Econometrica* 26.

[242] Daniel Kahneman, *Thinking, Fast and Slow* (Penguin 2012) https://cdn.penguin.co.uk/dam-assets/books/9780141033570/9780141033570-sample.pdf accessed 25 July 2025.

[243] Ale Smidts, *Kijken in het Brein: Over de Mogelijkheden van Neuromarketing* (Inaugural Lecture, Erasmus Universiteit Rotterdam 2002) (author's translation).

techniques from other scientific fields and consider whether these techniques can be used in marketing research'[244].

This period coincided with rapid advances in brain imaging technologies such as fMRI and EEG, which made it possible to observe brain activity non-invasively while individuals were exposed to marketing stimuli.

One of the most influential early studies in neuromarketing was the work of McClure et al., which examined consumer preferences for Coca-Cola and Pepsi, two drinks that are 'nearly identical in chemical composition, yet humans routinely display strong subjective preferences for one or the other'[245]. The study compared participants' brain responses when they drank the colas in anonymous (blind taste) and brand-cued conditions. Strikingly, the researchers found that 'brand knowledge for one of the drinks had a dramatic influence on expressed behavioral preferences and on the measured brain responses'[246].

The fMRI data revealed that when tasting without brand information, subjects' preferences correlated with activity in the ventromedial prefrontal cortex (VMPFC), a region associated with valuation and reward. However, when the brand was revealed, especially for Coca-Cola, brain regions related to memory and emotion, including the hippocampus and dorsolateral prefrontal cortex (DLPFC), became involved. The authors concluded that 'cultural influences dominate what we eat and drink'[247] and that marketing messages 'have insinuated themselves into the nervous systems of humans that consume the drinks'[248].

This research demonstrated for the first time that brand information can alter not only conscious preferences but also the neural processes underlying those preferences, providing a scientific basis for the power of branding.

Since then, neuromarketing has expanded to investigate not only product and brand preferences but also advertising effectiveness, package design, store environments, and pricing strategies. This growing field now encompasses a wide range of applications that go beyond academic research, involving practical tools for businesses aiming to optimize

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[244] ibid.

[245] SM McClure and others, 'Neural Correlates of Behavioral Preference for Culturally Familiar Drinks' (2004) 44(2) *Neuron* 379.

[246] ibid.

[247] ibid.

[248] ibid 380.

their marketing strategies. As Plassmann et al. point out, neuromarketing ‘refers to practitioner and commercial interest in neurophysiological tools … to conduct company-specific market research’[249], highlighting how firms increasingly use neuroscientific techniques to gain insights tailored to their own products, brands, or campaigns.

Other scholars have similarly highlighted that neuromarketing offers ‘cutting edge methods for directly probing minds without requiring demanding cognitive or conscious participation’[250]. This perspective underscores how neuromarketing allows researchers and marketers to access consumers’ subconscious reactions in ways that traditional surveys or interviews cannot capture.

Today, neuromarketing incorporates a variety of techniques beyond fMRI, including eye-tracking, biometrics, facial expression analysis, and behavioral experiments, making it a rapidly growing field at the intersection of science and business.

3.1.2 Neuromarketing techniques based on neurodata

As seen in the previous section, neuromarketing employs advanced neuroscience techniques to reveal consumers’ subconscious responses to marketing stimuli, offering insights that traditional tools like surveys or focus groups often cannot capture. By directly measuring the brain’s electrical or hemodynamic signals, these methods make it possible to understand how individuals truly perceive, evaluate, and decide about products, brands, and advertisements. The main techniques used in this field are electroencephalography (EEG), functional magnetic resonance imaging (fMRI), and functional near-infrared spectroscopy (fNIRS), each with specific strengths: EEG provides excellent temporal resolution to track rapid cognitive and emotional changes; fMRI offers high spatial resolution to identify which brain regions are involved in valuation and decision-making; and fNIRS offers a low-cost and mobile alternative for assessing activity in the superficial layers of the cortex, with a spatial resolution adequate for many research applications.

Specifically, it is widely acknowledged that EEG represents a “a non-invasive technique that measures the electrical activity of the brain through electrodes placed on the scalp.

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[249] H Plassmann, TZ Ramsøy and M Milosavljevic, ‘Branding the Brain: A Critical Review and Outlook’ (2012) 22(1) *Journal of Consumer Psychology* 18.

[250] C Morin, ‘Neuromarketing: The New Science of Consumer Behavior’ (2011) 48(2) *Society* 131.

… The most significant advantage of EEG is its millisecond temporal resolution, allowing it to capture cognitive processes as they change over time”[251]. Scholars also highlight how, on the other hand, fMRI is the dominant tool in cognitive neuroscience for mapping brain activity, offering ‘high spatial resolution for the precise localization of brain activity in deep’[252]. Finally, fNIRS is widely regarded as an accessible and mobile neuroimaging tool capable of capturing cortical activity at a moderate spatial resolution; ‘however, fNIRS has its limitations compared to fMRI and EEG. It can only measure activity in cortical areas and lacks the high temporal resolution of EEG’[253].

Central to understanding consumer decisions are brain regions like the medial prefrontal cortex (MPFC) and the nucleus accumbens (NAcc), which play key roles in reward processing and valuation:

> The MPFC serves various functions in valuation, affective regulation, and social cognition. … The NAcc serves as the central hub for the integration of neural networks involved in reward processes, goal-directed behaviors, changes in affective states, and motivation.[254]

Observing activation patterns in these areas can reveal preferences that consumers themselves might not be consciously aware of or able to articulate.

A critical advancement in neuromarketing research is the integration of diverse data types, like self-report, behavioral, and neural data, to improve the accuracy of consumer behavior predictions. Self-report data include traditional methods like questionnaires or interviews, but often fail to capture subconscious processes. Behavioral data involve observable actions such as gaze patterns or response times, providing objective indicators of what attracts attention or motivates action. Neural data, collected through EEG, fMRI, or fNIRS, instead capture unconscious brain responses. By combining these three, researchers can ‘offer effective predictions of consumer behavior and provide enhanced insights into consumer preferences and choices’[255].

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[251] Yimin Yao and Liyuan Wang, ‘Using Neural Data to Forecast Aggregate Consumer Behavior in Neuromarketing: Theory and Evidence’ (2024) *23 Journal of Consumer Behaviour* 2143.

[252] ibid 2153.

[253] ibid.

[254] ibid 2144.

[255] ibid 2142.

A crucial development emerging from the integration of self-report, behavioral, and neural data is the use of *data fusion* techniques, which allow researchers to combine multiple types of biosignals collected during neuromarketing experiments. This integration leads to a more complete and nuanced understanding of consumer responses by connecting what people say, what they do, and how their brain and body react subconsciously. As highlighted by Quiles Pérez et al., recent research shows 'a shift towards the fusion of diverse biosignals'[256], with tools like EEG and eye-tracking often used together to link brain activity with the specific elements of an ad that catch a consumer's gaze.

This approach goes beyond simply observing where someone looks or measuring their brainwaves separately: by bringing these signals together, data fusion can reveal whether visual attention to certain stimuli is actually accompanied by engagement or emotional reactions at a neural level. For example, a consumer might look at a product on screen, but only when the EEG data shows activation in reward-related areas can researchers infer genuine interest or excitement. According to the authors, 'the fusion of data from multiple sources demands advanced processing methodologies'[257], but it also provides richer and more reliable insights into what drives preferences and decisions.

Moreover, data fusion makes it possible to reduce ambiguity that comes from using a single signal. For instance, eye-tracking alone can show which parts of an ad are most noticed, but not whether that attention is positive, negative, or emotionally neutral; EEG or other biosignals can fill in this missing piece. This combined perspective helps marketers identify what aspects of a campaign are truly effective, and what may attract attention without generating positive responses.

3.2 Neurodata and consumer profiling

3.2.1 Neurodata in algorithmic and predictive consumer targeting

The integration of neurodata into algorithmic consumer targeting marks a significant evolution in the field of neuromarketing. Technologies like EEG and fMRI make it

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[256] Mario Quiles and others, 'Data Fusion in Neuromarketing: Multimodal Analysis of Biosignals, Lifecycle Stages, Current Advances, Datasets, Trends, and Challenges' (2024) 105 *Information Fusion* 102231.
[257] ibid.

possible to access unconscious cognitive and emotional responses to marketing stimuli. When this information is processed through artificial intelligence (AI) and machine learning (ML) algorithms, it enables marketers to develop highly refined models of consumer behavior; models that go beyond traditional profiling by incorporating indicators of attention, motivation, and emotional valence.

This use of neurodata in marketing automation is not merely theoretical: it is already being operationalized. As noted by Goncalves et al., 'the more unstructured data the AI/ML algorithms process, the more precise the output they provide to users'[258], highlighting the central role of neurodata in training advanced predictive systems. These systems can recognize neural patterns that correlate with specific consumer attitudes or intentions, then apply them to identify and segment audiences more effectively. Consumer responses recorded through neurotechnologies are transformed into 'meaningful patterns such as "level of mental acceptance of the message," "readiness to make a decision," or "current cognitive load"'[259], which are then fed into machine learning models. Unlike traditional targeting based on demographics or past behavior, this approach 'emphasizes aligning the marketing message with the user's mental state'[260], shifting digital advertising 'from a purely reactive tool to an interactive and real-time system'[261].

Beyond theoretical promise, neurodata-driven systems are already shaping advertising strategies across multiple sectors. In India, for instance, the integration of AI and neuromarketing in on-demand app ecosystems has enabled marketers to 'identify complex trends and make remarkably accurate predictions about customer preferences'[262], thereby tailoring experiences with unprecedented precision. Such applications have shown effectiveness not only in e-commerce, but also in other areas such as political campaigning[263], demonstrating the wide potential of this approach.

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[258] Marcus Goncalves, Yiwei Hu, Irene Aliagas and Luis Manuel Cerdá, 'Neuromarketing algorithms' consumer privacy and ethical considerations: challenges and opportunities' (2024) 11(1) *Cogent Business & Management* 2333063 2.

[259] Hamed Nozari, 'Cognitive Targeting and Neuromarketing Applications in AI-Driven Digital Advertising' (2025) 5(2) *Applied Innovations in Industrial Management* 54.

[260] ibid.

[261] ibid.

[262] Soummya Chowdhury and others, 'Role of Neuromarketing and Artificial Intelligence in Futuristic Marketing Approach: An Empirical Study' (2024) 4(2) *Journal of Informatics Education and Research* 560.

[263] See R Gupta, H Verma and AP Kapoor, 'Neuromarketing in predicting voting behavior: A case of National elections in India' (2023) *Journal of Consumer Behaviour*.

This operationalization reflects a broader transformation in the marketing paradigm: one that shifts from message delivery to interactive behavioral engagement. With the ability to interpret subconscious responses and emotional triggers, marketers are no longer limited to demographic or behavioral assumptions.

The use of neurodata in predictive targeting also raises significant ethical and social concerns when applied to audiences deemed more susceptible to persuasive techniques. ‘The digital marketplace presents unique challenges, especially for those traditionally considered vulnerable consumers’[264], and the collection of brain-related data, from attention patterns to emotional states, can be leveraged to customize advertising in ways that subtly bypass conscious decision-making. This is particularly concerning when nudging techniques[265] are deployed in combination with real-time biometric insights, allowing companies to steer individuals toward commercial behaviors they might not have otherwise chosen freely.

Among the most advanced tools in this domain are emotion recognition systems, which utilize facial coding, voice analysis, and physiological signals to infer consumers’ emotional reactions. These systems are increasingly integrated into digital platforms, making emotional data part of the predictive targeting ecosystem. In this sense, ‘the role of consumers in marketing has shifted from passive recipient to emotionally engaged participant, and brands can build deeper emotional connections with consumers through real-time emotional feedback’[266]. This approach reflects a growing reliance on affective computing[267], a field that blends artificial intelligence with emotional intelligence to make human-computer interaction more intuitive and persuasive.

Such developments heighten the power imbalance between corporations and individuals, particularly when consent is opaque or difficult to refuse. As emotional responsiveness becomes a variable in targeting algorithms, the line between persuasion and manipulation grows increasingly blurred. The ethical implications of using neurodata to predict and

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[264] Francesca Bertelli, ‘Consumer Education in the Digital Era: Re-shaping the Vulnerable, the Average and the Informed Consumer?’ in Salvatore Orlando (ed), *Profili giuridici del neuromarketing. Annuario 2023–2024 OGID – Osservatorio Giuridico sull’Innovazione Digitale* (Sapienza Università Editrice 2025) 30. The article explains how the Italian Consumer Code differentiates between the average consumer and the vulnerable consumer, highlighting the importance of providing specific legal protections to the latter, especially in digital contexts.

[265] See n 99.

[266] Huanyu Liu, ‘The Application Prospects of Consumer Emotion Recognition Technology in Marketing Strategies’ (2025) 6(3) *Modern Economics & Management Forum* 334.

[267] See n 66.

influence behavior demand closer scrutiny, especially when these strategies operate beneath the level of conscious awareness.

3.2.2 How profiling affects autonomy and consumer decisions

The increasing reliance on profiling and targeted marketing practices in digital environments, especially through the Internet of Things (IoT), raises pressing questions about consumer autonomy. Profiling (automated data analysis that creates individualized consumer profiles) has enabled marketers to predict behavior with unprecedented precision. These predictions are then used to influence consumer decisions, often without the consumer's full awareness or consent.

In this context, profiling,

> ‘signifies a shift from previous modes of mass communication (advertisements that were “broadcast” to an anonymous mass of consumers) and the mass production of products and services to far more tailored and personalised ways of engaging with customers’[268].

Smart devices, ranging from watches to refrigerators, continuously collect situational and behavioral data that are transformed into hyper-personalized commercial interactions. Unlike traditional advertising, these devices allow businesses to dynamically alter prices, conditions, and services based on perceived consumer willingness or urgency, undermining the concept of a fair marketplace.

Such strategies blur the line between persuasion and manipulation. A consumer interacting with a fitness app might receive nudges (algorithmically derived suggestions) that align not just with their health goals, but also with insurance company interests or retailer promotions. This dynamic shapes not only choices but also the conditions under which choices are made: ‘consumers no longer simply buy a product in exchange for money. ‘Paying with your data’ will often become part of the deal’[269]. The

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[268] Natali Helberger, ‘Profiling and Targeting Consumers in the Internet of Things – A New Challenge for Consumer Law’ (6 February 2016) https://ssrn.com/abstract=2728717 (accessed 12 July 2025).

[269] ibid 7.

commodification of personal information transforms user behavior into a transactional currency, shifting power toward corporations.

The autonomy issue becomes more acute when profiling is combined with predictive inferences. Corporations increasingly rely on algorithmic techniques not just to observe past behavior, but to anticipate and shape future actions. Büchi et al. highlight that 'corporations primarily create profiles to more effectively position relevant, targeted ads'[270], posing a significant risk of 'malicious uses of the data'[271].This predictive capacity opens the door to discriminatory pricing, opaque exclusions, and behavioral nudging, all of which can skew consumer decision-making away from authentic preferences.

The same analysis explains the emergence of "chilling effects" in response to pervasive profiling. These refer to the behavioral modifications consumers may adopt to avoid scrutiny or algorithmic misjudgment. As the authors explain, chilling effects 'can manifest as self-censorship, self-restraint, or as silencing effects'[272], where users alter their digital behavior not to express genuine preferences, but to avoid negative consequences, such as increased insurance premiums or exclusion from certain offers. This atmosphere of latent surveillance compromises the consumer's capacity for free choice and authentic self-expression.

As seen in the previous section[273], these concerns become even more pronounced when profiling intersects with neuroscientific methods designed to tap into unconscious emotional and cognitive processes. By leveraging neural data, marketers can design highly personalized stimuli that bypass rational deliberation, appealing instead to affective triggers. In fact, 'neurotechnology enables marketers to refine persuasion attempts using noninformative or misinformative content, with the potential to trigger very positive affective responses in consumers'[274]. This means that persuasion may be based less on helping consumers make informed choices and more on eliciting emotional reactions that align with commercial goals.

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[270] Moritz Büchi and others, 'The Chilling Effects of Algorithmic Profiling: Mapping the Issues' (2020) 36 *Computer Law & Security Review* 105367.

[271] ibid.

[272] ibid 2.

[273] See par. 3.2.1.

[274] R Mark Wilson, Jeannie Gaines and Ronald Paul Hill, 'Neuromarketing and Consumer Free Will' (2008) 42(3) *The Journal of Consumer Affairs* 404.

Such practices directly raise the concern articulated by Herbert Jack Rotfeld, who warns that ethical justification based solely on consumer demand is flawed, particularly when consumers 'can't know that they should want'[275] something. Profiling through neuromarketing risks reinforcing this gap: consumers may respond positively to stimuli that exploit their neural predispositions, without fully understanding what is being sold, or why they desire it. The appearance of preference becomes a substitute for genuine interest or need. In this way, profiling doesn't just serve demand, it helps manufacture it, often without regard to the consumer's actual well-being or long-term interest.

3.2.3 The subtle line between influence and manipulation

Neuromarketing can bridge the gap between what consumers say and what they feel, while traditional market research often fails to detect the subconscious motivators behind purchasing decisions. In this sense, 'reducing the 'gaps' between the consumers' subconscious and their behaviour is one of the major challenges facing sellers today. Neuromarketing provides the opportunity to overcome these shortcomings'[276]. Magnetic resonance imaging and other neuroimaging tools allow researchers to observe how stimuli trigger specific brain responses. The promise of this technology lies in its capacity to fine-tune product development and advertising in a way that resonates more deeply with consumer desires. Yet, the same capacity invites significant ethical scrutiny: when companies know what we want even before we do, where does that leave our autonomy? This ethical tension is also reflected in recent theoretical developments that attempt to clarify the distinction between neuromarketing and related fields like neuroeconomics. While neuroeconomics focuses on '"choices"'[277], neuromarketing focuses on '"influence"'[278], that is, shifting distributions of behavior across scales of measurement. "Influence", as described, is not inherently negative; it's the backbone of many socially constructive endeavors like education or public health. However, as some authors caution,

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[275] Herbert Jack Rotfeld, 'Mistaking a Marketing Perspective for Ethical Analysis: When Consumers Can't Know That They Should Want' (2007) 24 *Journal of Consumer Marketing* 383–84.

[276] Larisa Dragolea and Denisa Cotîrlea, 'Neuromarketing – Between Influence and Manipulation' (2011) 3 *Polish Journal of Management Studies* 80.

[277] Hans C Breiter and others, 'Redefining neuromarketing as an integrated science of influence' (2015) 8 *Frontiers in Human Neuroscience* 1073, 1.

[278] ibid.

‘influence can affect choice through many cognitive modalities’[279], including attention, memory, and emotion, all of which can be unconsciously hijacked if not handled responsibly.

And this is precisely where the controversy sharpens. While some persuasive practices are clearly coercive or harmful, many others are more subtle, and harder to detect or regulate. As Nita Farahany warns, ‘the more difficult cases to resolve … are the subtler influences that shape our everyday decision-making and that are quickly becoming normalized’[280]. These influences don’t have to be subliminal to be effective; in fact, ‘most practices are not hidden at all, we just don’t realize how they influence our behavior’[281]. The concern is especially acute when seemingly ordinary design choices or message framings start to erode our capacity for self-direction. For instance, ‘we may want to stop checking Instagram every five minutes, but cleverly timed notifications compulsively draw us back in’[282], a modern example of how external cues can override our better judgment. The ethical discomfort is amplified by the fact that the very features which make neuromarketing so appealing, its objectivity, precision, and predictive power, are the same ones that make it prone to abuse.

Despite these concerns, defenders of neuromarketing argue that it’s not about manipulation but optimization. As Steve Quartz, professor of philosophy at California Instute for Technology and researcher in neuroscience, explained in a 2006 interview, ‘it’s more a means of measuring preferences rather than a technique for manipulating choice’[283]. His approach, based on functional brain imaging, is intended to complement traditional behavioral research by offering new insights into decision-making processes that often escape introspection. In the same vein, many researchers and practitioners highlight that the idea of neuromarketing as a powerful manipulative tool is often exaggerated. As noted in the related academic literature, ‘despite its intuitive appeal, there has been skepticism from the beginning about our ability to directly extract hidden

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[279] ibid.

[280] Nita A Farahany, ‘Neuromarketing and the Battle for Your Brain’ (Wired, 14 March 2023) https://www.wired.com/story/neuromarketing-philosophy-ethics/ accessed 12 July 2025.

[281] ibid.

[282] ibid.

[283] ‘Academic Experts Sound Alarm Over Influence of Film Schools on Graduates’ *The Guardian* (20 June 2006) https://www.theguardian.com/film/2006/jun/20/academicexperts.highereducation accessed 12 July 2025.

information from neural data that are of interest to marketers'[284]. This reflects a broader understanding that the complexity of human cognition, combined with the current limitations of neuroscientific methods, makes it unlikely that marketers can gain unfettered access to consumers' unconscious drives.

Moreover, as it usually happens with emerging technologies, the real risks and opportunities are frequently misjudged. Some authors point out that 'as is often the case with cutting-edge technology in industries undergoing rapid transformations, there has been a widespread tendency to overestimate both effectiveness and limitations'[285]. This caution suggests that while neuromarketing may eventually lead to valuable advances, it is far from the omnipotent force some fear it to be.

Rather than replacing established methodologies, neuroscientific tools are increasingly seen as a useful addition to the existing marketing research toolkit. 'By viewing traditional and brain-based approaches as complements rather than substitutes' the author argues, 'marketers and firms can combine them in novel and innovative ways in order to generate and validate customer insights that are fundamental to strategy formulation'[286]. In this view, neuromarketing serves less as a means of control and more as a way to enhance understanding[287], particularly of the implicit or emotional factors that traditional methods might overlook.

Ultimately, neuromarketing sits at a delicate intersection: it holds the potential to enrich our understanding of consumer behavior, yet it also risks crossing ethical boundaries when influence begins to resemble manipulation. Its growing precision makes it both valuable and potentially intrusive. As the line between helpful guidance and covert persuasion continues to blur, the challenge lies not just in what neuromarketing can do, but in what it should be allowed to do.

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[284] Ming Hsu, 'Neuromarketing: Inside the Mind of the Consumer' (2017) 59(4) *California Management Review* 11.

[285] ibid 6.

[286] ibid 7.

[287] See Yu-Ping Chen, Leif D Nelson and Ming Hsu, 'From "Where" to "What": Distributed Representations of Brand Associations in the Human Brain' (2015) 52(4) *Journal of Marketing Research* 453. The study suggests that neural responses elicited through fMRI strongly align with traditional self-report measures of brand personality. This implies that key consumer insights obtained via neurotechnologies can in fact be replicated using more conventional methods, supporting the idea that neuroscience may validate rather than replace established marketing research tools.

3.3 Anticipatory Shipping and the New Frontiers of Predictive Marketing

3.3.1 What Is Anticipatory Shipping? From Forecast to Fulfillment

Anticipatory shipping is a revolutionary approach to e-commerce logistics that uses predictive analytics and customer data to ship products to customers before they actually place an order. At the heart of this concept is Amazon, the retail giant that patented the method in 2013 under the title 'Method and System for Anticipatory Package Shipping' (US Patent No. US8615473B2). The essence of this system is to anticipate demand so precisely that products begin their journey to customers before the final delivery address is even known.

According to the patent, the system involves: 'packaging one or more items as a package for eventual shipment to a delivery address … without completely specifying the delivery address at time of shipment, and while the package is in transit, completely specifying the delivery address for the package'[288]. This method is enabled by the massive amount of data Amazon collects on user behavior: browsing history, shopping patterns, wish lists, and even time spent on product pages. It's an aggressive form of logistics optimization where efficiency is derived not just from speed of shipping, but from knowing what people want before they do.

The predictive mechanism at the core of anticipatory shipping analyzes a combination of individual user data and broader consumer trends. 'Amazon knows what we like, what we need, before we know it ourselves. … By profiling customers shopping desires, Amazon is able to pack and dispatch goods it guesses customers will buy preemptively'[289]. This mechanism enables Amazon to relocate products to regional distribution centers, trucks, or even delivery hubs in anticipation of upcoming purchases. In doing so, the time between the customer placing an order and receiving the product can be reduced to just a few hours, even for first-time buyers.

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[288] Amazon Technologies Inc, *Method and system for anticipatory package shipping*, US Patent 8615473 B2 (24 December 2013).

[289] Domenico Talia, 'Anticipatory Shipping' in *Big Data and the Computable Society: Algorithms and People in the Digital World* (World Scientific 2019) 19.

More specifically, Amazon’s able to ‘ship one or more items in your general direction before you even purchase said items’[290], giving the company the strategic latitude to position packages within a target zone before any order is placed. This hub-based pre-shipping process enables Amazon to bring inventory closer to customers, through carrier vehicles, local hubs, or postal areas. The patent envisions packages being shuttled around a delivery region after leaving a fulfillment center, eventually targeting individual zip codes or cities to minimize cross-country transit time and thereby dramatically accelerate delivery windows[291]. This reshapes fulfillment from a reactive operation into a tactical, location-based anticipation model, fundamentally reframing the relationship between intent and inventory. This approach can minimize perceived delivery delays, lower shipping costs through strategic routing, and improve inventory turnover.

The method also makes it easier to offer targeted promotions if a forecast turns out to be inaccurate. For example, if a predicted purchase doesn't happen, Amazon may offer a discount on the pre-shipped product to someone nearby, rather than returning it to the warehouse.

Despite its conceptual sophistication and operational flexibility, however, anticipatory shipping has yet to achieve its full potential. In fact, the new technique, as originally envisioned, has not fully materialized. As noted in a 2023 article revisiting the patent ten years later, ‘it appears that the anticipatory shipping concept was not put into action, at least not as proposed’[292]. The article further explains that this limited implementation was due, in part, to logistical and infrastructural limitations: ‘the anticipatory shipping patent relied too heavily on common-carrier networks and predictability, and not enough on forward storage capacity local to urban areas’[293]. These shortcomings suggest that while the concept held theoretical promise, its practical application encountered significant friction within existing distribution frameworks.

This gap between vision and execution is not unique to Amazon’s model; in fact, similar logistical ambitions have surfaced in earlier technological contexts.

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[290] David Jafari, *Amazon’s Anticipatory Shipping Patent Explained* (Jafari Law Group, 25 February 2014) https://jafarilawgroup.com/amazon-anticipatory-shipping-patent-explained/ accessed 13 July 2025.

[291] ibid.

[292] LV Staff, *Amazon and Anticipatory Shipping: Revisiting This Highly Publicized 2013 Patent Ten Years Later*(Logistics Viewpoints, 6 September 2023) https://logisticsviewpoints.com/2023/09/06/amazon-anticipatory-shipping/accessed 13 July 2025.

[293] Ibid.

While anticipatory shipping is often presented as a cutting-edge innovation, a web article[294] points out that similar ideas were already being explored in the 1990s, but in a different technological context: is the case of Non Stop Logistics, a software company spun off from Stanford University. Rather than focusing on individual-level predictions, the firm aimed to forecast the aggregate demand of fast-moving consumer goods in specific regions and time frames, for instance, the expected consumption volume in a city over a weekend. The underlying principle was that area-level forecasting could be more accurate than detailed store-by-store predictions.

According to the article, the company's strategy was to sign agreements with consumer goods manufacturers, receive bulk deliveries based on its software's forecasts into a regional distribution center, and then deliver products to individual retail points using more granular inventory analysis. Moreover, a *Forbes* article[295] questioned whether Amazon's anticipatory shipping should have been patentable at all, given the conceptual similarity to earlier logistical models and the lack of genuine novelty. However, while conceptually similar, Amazon's approach stands apart due to the advanced technologies now underpinning its predictive capabilities.

From a technological standpoint, Amazon's strategy relies on sophisticated machine learning algorithms that evolve with every click and purchase. Amazon's system makes use of 'predictive analytics tools and a massive trove of Amazon customer data'[296]: the longer a customer engages with Amazon, the more data points are available to refine these predictions. As a result, accuracy improves, and the system becomes increasingly effective at meeting demand before it's explicitly voiced.

Ultimately, anticipatory shipping stands as a data-driven logistical strategy, one that is only as powerful as the quality and granularity of the information it relies on. The entire system hinges on Amazon's ability to collect, analyze, and act upon vast amounts of user

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[294] Amazon brevetta la consegna che parte ancora prima dell'ordine del cliente' (*Digital4.biz*, 28 January 2014) https://www.digital4.biz/supply-chain/amazon-brevetta-la-consegna-che-parte-ancora-prima-dell-ordine-del-cliente/accessed 14 July 2025.

[295] See Steve Banker, 'Amazon and Anticipatory Shipping: A Dubious Patent' (*Forbes*, 24 January 2014) https://www.forbes.com/sites/stevebanker/2014/01/24/amazon-and-anticipatory-shipping-a-dubious-patent accessed 13 July 2025.

[296] Megan Ray Nichols, *Amazon Wants to Use Predictive Analytics to Offer Anticipatory Shipping* (*SmartData Collective*, 16 January 2018) https://www.smartdatacollective.com/amazon-wants-predictive-analytics-offer-anticipatory-shipping/accessed 14 July 2025.

data in real time. It is therefore essential to understand how Amazon gathers and structures such data, a question explored in the following section.

3.3.2 Predicting the Consumer: Between Big Data and Logistics

The idea that companies can know what we want before we do might once have sounded like science fiction or divination[297]. Today, however, predictive technologies driven by massive datasets and advanced machine learning make that vision increasingly real. Amazon's anticipatory shipping system, once viewed as merely ambitious, now embodies the deeper transformation of consumer behavior into a predictable, actionable sequence, sometimes even before conscious thought takes place.

At the heart of this transformation lies Big Data. Every click, scroll, or second spent hovering over a product page becomes part of a larger pattern, a behavioral footprint that can be used to forecast future purchases. Amazon’s model, based on this data, allows products to be moved closer to customers even before an order is placed. In this sense, Amazon, as one of the most powerful retailers in the current digital landscape:

> have a boat-load of customer data to leverage when deciding what kind of products consumers will be looking for on a regular basis. With more data comes more accurate predictive analytics, which in the end makes-or-breaks how successful an anticipatory shipping strategy will be[298].

Yet this is not simply a matter of optimizing warehouse logistics. Amazon’s anticipatory shipping model also heavily relies on its capacity for real-time data processing, which transforms static forecasting into continuous decision-making. Rather than waiting for demand signals to accumulate, the system actively monitors browsing behavior, purchase cycles, and geographic trends as they unfold: ‘by combining real-time data streams with

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[297] See Eva-Maria Nyckel, ‘Ahead of Time: The Infrastructure of Amazon’s Anticipatory Shipping Method’ in Andreas Volmar and Karin Stine (eds), *Media Infrastructures and the Politics of Digital Time: Essays on Hardwired Temporalities*(Amsterdam University Press 2021) 263. In the text, the author reconstructs Elena Esposito’s comparative analysis in which algorithmic predictions are likened to ancient divination practices, framing algorithmic forecasting as a modern form of prophecy.

[298] Will Amazon’s Anticipatory Shipping Strategy Be a Game Changer for Retailers?’ (*Retail TouchPoints*, 16 January 2014) https://www.retailtouchpoints.com/blog/will-amazons-anticipatory-shipping-strategy-be-a accessed 14 July 2025.

historical data and machine learning models, Amazon can make split-second decisions about where to position inventory and when to initiate shipments'[299]. This dynamic approach allows the company not just to respond to demand but to act ahead of it, positioning inventory where it is most likely to be needed even before the consumer completes a transaction.

This kind of anticipatory logic would not be possible without the layered capabilities of Big Data Analytics (BDA), which has become foundational in modern supply chain management. As outlined in recent studies, BDA is typically divided into three categories: 'predictive analytics produces forecasts about future events, descriptive analytics provides insights into past events, and prescriptive analytics provides recommendations for future actions to aid in decision-making'[300]. These functions operate in a continuum, allowing companies like Amazon not only to understand customer behavior retrospectively but to also simulate possible futures and act upon them. In the context of logistics, predictive and prescriptive analytics become especially valuable. Using real-time data inputs, from radio-frequency identification (RFID) tags, GPS-enabled devices, or customer interactions, Amazon is able to constantly refine the positioning of inventory and streamline its delivery network. As the same source notes, 'big data gathered from participants in the distribution network, such as carriers and logistics service providers, can be used in logistics to improve the efficiency of transportation networks'[301]. This signals a shift from reactive to proactive logistics, where decision-making is no longer tied to traditional triggers like checkout confirmation, but instead emerges from a complex interplay of user activity, algorithmic inference, and infrastructural readiness. Furthermore, the use of BDA in demand shaping opens up new possibilities for influencing consumer behavior. By leveraging individual-level data, Amazon can generate personalized promotions or discounts to steer customers toward specific products thus not only forecasting demand but actively producing it.

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[299] Case Study: Amazon's Anticipatory Shipping—Leveraging Data as a Strategic Asset' (*VitalStatistix Research Academy*, 2 March 2024) https://vitalstatistix.org/content/2024/03/02/case-study-amazons-anticipatory-shipping/?i=2 accessed 14 July 2025.

[300] Pratiksha Nayak and Abhishek Nair, 'Anticipatory Shipping: An Overview on Implementation of Anticipatory Shipping Through a Managerial Perspective' (2023) 10(3) *EPRA International Journal of Economics, Business and Management Studies.* 18.

[301] ibid.

This increasingly seamless integration between logistics and data-driven prediction raises a critical question: what kind of data fuels these anticipatory systems, and how far can, or should, companies go in interpreting consumer intent? As Amazon’s model shows, the effectiveness of anticipatory shipping hinges not just on the volume of data collected, but on the depth of insight it can extract from users' behavior. But when prediction moves toward preempting desires before they are consciously formed, the boundaries between consumer preference and corporate influence begin to blur. This brings us to a more complex intersection: what happens when anticipatory shipping converges with neuromarketing? The following section explores the implications of this entanglement, questioning the ethical and commercial risks of turning subconscious signals into logistical decisions.

3.3.3 Toward an Anticipatory Neuromarketing?

In its current form, anticipatory shipping relies heavily on the observation and analysis of users’ digital behavior. This behavioral data allows predictive systems to infer purchasing intentions, preferences, and even, to some extent, emotional inclinations. As previously discussed, this type of information may fall under the broader definition of mental data (‘any data that can be organized and processed to infer the mental states of a person, including their cognitive, affective, and conative states’[302]). From this perspective, anticipatory shipping already operates within a framework that implicitly incorporates aspects of mental life, albeit through indirect and behavioral proxies.

However, the ongoing development of neurotechnologies may soon deepen this integration. Unlike traditional behavioral tracking, these tools are capable of capturing direct neurophysiological signals, what we typically refer to as neurodata. As these technologies become more refined and accessible, they could be incorporated into anticipatory systems, offering new layers of granularity and immediacy. In such a scenario, the anticipatory logistics model would no longer rely solely on what users do, but potentially on what they feel or even think, moving prediction closer to pre-conscious intention and reshaping the boundaries between desire, data, and delivery.

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[302] See n 68.

This speculative horizon begins to materialize with real-world developments such as Synchron's integration of brain-computer interfaces (BCIs) with Amazon Alexa[303]. In 2023, a patient named Mark, living with ALS, became the first person to control Alexa not with speech or touch, but with neural activity alone. Originally designed to assist people with paralysis in regaining digital agency, the BCI translates thoughts into commands, allowing Mark to browse, call, watch television, or shop online using only his brain. As the article notes, 'with the Amazon integration, he can control Alexa … to turn the lights on and off in his house, watch TV, make video calls, play music, control his Ring security camera, read books on Kindle, and shop on Amazon'[304].

Though presented as a medical breakthrough, this integration also carries significant commercial and conceptual implications. With BCI-Alexa connectivity, Amazon is not merely interpreting behavior, it is interfacing with pre-verbal cognition. That a product search, media selection, or purchase can be initiated purely by intent, without speaking, clicking, or tapping, represents a profound leap in the anticipatory logic of commerce. If a system can register what a person wants before they act, and respond accordingly, then the infrastructure for neural anticipatory shipping is already emerging.

In such a trajectory, we may witness the development of a true *anticipatory neuromarketing* model, one in which cognitive states, emotional triggers, and neural intentions become direct inputs for shaping not only what is marketed, but what is shipped, when, and to whom.

This means that the anticipatory model may no longer need to infer desire from browsing history, purchase frequency, or regional demand. Instead, it could evolve toward a direct neural feedback loop, where commercial platforms like Amazon read moment-to-moment changes in attention, curiosity, or reward response, and translate those into actionable logistics. As Synchron's CEO Thomas Oxley explains, the company is developing ways to map brain signals to interactions such as 'scroll, click, drag, menu drop-down, back— all these different things that we use our fingers to do' with the goal of creating 'product

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[303] The analysis is based on the content of Emily Mullin, 'This Brain Implant Lets People Control Amazon Alexa With Their Minds' *WIRED* (16 September 2024) https://www.wired.com/story/synchron-amazon-alexa-brain-computer-interface-bci/ accessed 13 July 2025.

[304] ibid.

features to control operating systems'[305]. These same interactions underpin the architecture of e-commerce.

In this context, the fulfillment cycle risks becoming an involuntary circuit, where subconscious inclinations trigger predictive delivery chains, without any articulated intent. A thought, a flicker of interest, a momentary neural pattern might be all it takes. While this could redefine convenience, it also collapses the distance between inner mental life and external commercial action. Shopping, once an intentional act, risks becoming an ambient process, where agency is reduced to a stream of data parsed and executed by algorithms operating faster than conscious awareness.

In conclusion, the progression from behavioral data to direct neural input marks a pivotal shift in the anticipatory shipping paradigm. What began as inference from digital traces now edges toward the real-time capture of mental states, raising profound questions about autonomy, consent, and the nature of agency. The integration of BCIs into commercial ecosystems suggests a future in which desire is not expressed, but detected, a shift that could transform shopping from a conscious act into an automated cognitive response. While this may enhance efficiency and personalization, it also risks bypassing deliberation entirely, making fulfillment a function of fleeting neural activity.

Yet, other trajectories remain possible. As one scenario suggests, 'Amazon could use IoT sensors to track the usage and depletion of household items … and automatically initiate anticipatory shipments when supplies run low'[306], enabling predictive logistics without venturing into neurocognitive data. Also, 'predictive analytics and real-time data processing could be used to optimize supply chains in industries like manufacturing, healthcare, and energy'[307]. Whether driven by neural signals or environmental cues, the challenge ahead is to ensure that prediction enhances human experience without diminishing human agency. The future of commerce may be anticipatory, but it must also remain intentional.

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[305] ibid.

[306] 'Case study: Amazon's Anticipatory Shipping' (n 299).

[307] ibid.

3.4 Legal challenges and regulatory pathways in neuromarketing

3.4.1 European and international regulatory framework

The increasing use of neurotechnologies in consumer markets has attracted substantial legal and regulatory attention within the European Union. These technologies, especially when combined with artificial intelligence, enable the extraction and processing of neural data to infer cognitive and emotional states, health conditions, and behavioral tendencies. In this context, the regulation of neuromarketing, the use of such data to guide or influence consumer behavior, is primarily governed by three major European legal instruments: the General Data Protection Regulation[308] (GDPR), the Digital Services Act[309] (DSA), and the Artificial Intelligence Act[310] (AI Act).

The General Data Protection Regulation (GDPR) applies directly to the collection and processing of neural data because such data can fall under the category of personal data as defined in Article 4(1), which includes 'any information relating to an identified or identifiable natural person'. Furthermore, when the processing of neural data reveals sensitive insights such as mental health conditions or unique biometric identifiers, it qualifies as special categories of personal data under Article 9[311]. The GDPR prohibits the processing of special category data unless specific exceptions apply. Among these, the most relevant to neuromarketing is explicit consent from the data subject, as detailed in Article 7[312] and Article 9(2)(a)[313].

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[308] 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) [2016] OJ L 119/1

[309] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (Text with EEA relevance) OJ L 277, 27.10.2022.

[310] European Parliament and Council Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts [2024] OJ L236/1.

[311] GDPR, art 9: "*Processing of personal data revealing 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 shall be prohibited.'*

[312] GDPR, art 7: sets out the conditions for valid consent, requiring that it be freely given, specific, informed and unambiguous, and that data subjects must be able to withdraw their consent at any time.

[313] GDPR, art 9(2)(a): provides that the general prohibition on processing special categories of personal data does not apply where the data subject has given explicit consent for one or more specified purposes, unless Union or Member State law prohibits such consent from lifting the restriction.

Article 22 addresses automated decision-making and profiling, granting individuals the right not to be subject to decisions based solely on automated processing, including profiling, that significantly affect them. However, paragraph 2 of the same article provides exceptions to this rule, allowing such processing where it is necessary for entering into or performing a contract, is authorised by Union or Member State law providing suitable safeguards, or is based on the data subject's explicit consent.

Article 22 relevant for neurotechnological applications that may automatically profile individuals based on their neural or ocular responses. Profiling, as defined in Article 4(4)[314], encompasses the automated evaluation of aspects related to a natural person's behavior, preferences, or psychological tendencies, a common practice in neuromarketing strategies that aim to influence consumers' choices through personalization and emotional targeting.

Under Article 25 on privacy by design and privacy by default[315], and Article 35 on data protection impact assessment[316], data controllers must implement technical and organizational safeguards from the design phase and assess potential high risks to fundamental rights, conditions that are inherently met when using neurotechnology in marketing contexts. For minors, the GDPR requires additional safeguards[317], including the obligation to obtain consent from a parent or guardian and ensuring that the minor can freely withdraw from data processing. However, for other vulnerable groups such as the elderly or people with disabilities, the regulation does not explicitly provide tailored rules, even though these groups may have diminished capacity to give informed consent regarding complex neurotechnological processing[318].

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[314] GDPR ,art. 4(4): "*profiling' means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements;"*

[315] GDPR, art 25: introduces the principles of privacy by design and by default, requiring data controllers to implement appropriate technical and organisational measures to integrate data protection into the development of processing activities (design) and to ensure that, by default, only personal data necessary for each specific purpose are processed (default).

[316] GDPR, art 35: requires data controllers to carry out a data protection impact assessment when a type of processing, in particular using new technologies, is likely to result in a high risk to the rights and freedoms of natural persons, in order to assess and mitigate such risks before beginning the processing.

[317] GDPR, art 8: provides that where information society services are offered directly to a child, the processing of personal data is lawful only if the child is at least 16 years old, or if consent is given or authorised by the holder of parental responsibility; Member States may lower this age to 13. The controller must make reasonable efforts to verify such consent. Recital 38 further emphasises the need for specific protection of children's personal data, as they may be less aware of the risks involved.

[318] See par. 3.4.3

The Digital Services Act (DSA), as part of the European strategy for a safer digital space, includes provisions aimed at protecting users from manipulative online practices, also giving particular attention to minors. Article 28 imposes obligations on online platforms accessible to minors, requiring them to 'put in place appropriate and proportionate measures to ensure a high level of privacy, safety, and security'[319], and 'not present advertisements on their interface based on profiling … using personal data of the recipient of the service when they are aware with reasonable certainty that the recipient of the service is a minor'[320]. These obligations are further contextualised in recitals 71 and 81, which highlight the importance of implementing tools such as age verification and parental controls to mitigate risks to minors and to safeguard their well-being in the online environment.

Article 34 further expands the scope of platform accountability: it requires large platforms to identify and assess systemic risks, including those stemming from algorithmic systems or interface designs that could exploit users' vulnerabilities, lead to mental health issues, foster behavioral addiction, or negatively impact public health and well-being, especially for children and adolescents. These provisions indirectly address neuromarketing practices that could, through brain-computer interface data, eye-tracking inputs, or emotional profiling, result in persuasive content tailored to exploit cognitive weaknesses.

The Artificial Intelligence Act (AI Act), the first comprehensive legislative framework on artificial intelligence in the EU, introduces direct and indirect rules relevant to neurotechnological applications. Article 5 prohibits the use of AI systems that employ subliminal techniques or manipulative methods to distort human behavior[321] or exploit individual or group vulnerabilities based on age, disability, or economic or social condition[322]. These prohibitions extend to neurotechnologies, including brain-computer interface devices and emotion-recognition systems, particularly when used in commercial or marketing contexts. The Act emphasizes that such manipulative AI systems may operate without the user's awareness or capacity to resist, potentially infringing upon their freedom of choice. Examples include virtual reality environments and brain-computer

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[319] DSA, art 28(1).

[320] DSA, art. 28 (2)

[321] AI Act, art 5(1)(a).

[322] AI Act, art 5(1)(b).

interfaces that deliver imperceptible audio or visual stimuli designed to subconsciously influence user behavior[323].

Articles 6 and Annex III of the Artificial Intelligence Act classify certain AI systems, such as emotion recognition and biometric categorization, as high-risk applications when used in specific contexts, including access to education, employment, and essential services. These systems are subject to a comprehensive set of obligations set out in Articles 8 to 15, including risk management, data governance, technical documentation, record-keeping, and human oversight. Separately, Article 50 imposes transparency obligations for AI systems that interact directly with individuals or generate synthetic content, requiring that users be informed that they are interacting with an AI system, unless this is obvious to a reasonably well-informed, observant, and circumspect person. The notion of what constitutes "obvious" remains open to interpretation[324]. These transparency and oversight requirements are particularly relevant in the context of neuromarketing technologies, such as eye-tracking systems, which collect and process detailed ocular data, like gaze direction, blink rate, and pupil dilation, to infer emotional states and consumer preferences.

Although not specific to neurotechnologies, the Unfair Commercial Practices Directive of 2005[325] provides general protections against misleading and aggressive marketing[326]. These rules can be invoked against manipulative neuromarketing practices, especially if they target or exploit vulnerable individuals. However, the directive does not yet address the sophisticated, unconscious, and AI-driven influence that characterizes modern neuromarketing techniques.

As examined so far, the regulation of neuromarketing and neurotechnologies in the European Union currently relies on a combination of existing legal instruments, including the General Data Protection Regulation for the protection of personal and sensitive data, the Digital Services Act for platform responsibility and protection of minors, and the

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[323] AI Act, recital n. 29

[324] See par. 3.4.2

[325] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, art 5–6 (‘Unfair Commercial Practices Directive’).

[326] Unfair Commercial Practices Directive: Article 5(4) defines unfair commercial practices as those that are misleading or aggressive; Articles 6 and 7 specify what constitutes misleading actions and omissions, such as providing false information or omitting material details likely to affect consumer decisions; Articles 8 and 9 define aggressive practices, including harassment, coercion, or undue influence that significantly impairs the consumer’s freedom of choice.

Artificial Intelligence Act for regulating high-risk AI and banning manipulative systems. While these frameworks provide a foundation for data protection, transparency, and non-manipulation, their effectiveness depends heavily on enforcement, interpretation, and integration. Moreover, the lack of explicit recognition of inferred data as a protected category under the GDPR presents a regulatory blind spot[327], particularly critical given the predictive power of such data in neuromarketing contexts.

As the technological basis of neuromarketing continues to rely on profiling and data-intensive techniques, the interplay of these instruments becomes central to the actual application of the law.

Beyond the European Union, the regulation of neuromarketing is shaped by broader international legal frameworks, though these are often more general in scope. Instruments such as the OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data[328] and the Council of Europe's Convention 108+[329] serve as foundational references in international data protection. These frameworks establish high-level principles, such as fairness, transparency, and data minimization, that apply to the processing of personal and sensitive data, including those derived from neuromarketing techniques. Although they do not specifically address neurotechnology or neuromarketing, their principles have been integrated into regional and national laws, creating indirect regulatory effects. For example, article 6 of the Convention 108+ requires special protection for certain categories of sensitive data, such as genetic data, biometric data and personal data, which may be relevant when neuromarketing practices involve the processing of intimate or revealing personal information.

Similarly, the OECD Guidelines emphasize informed consent and purpose limitation[330], which are relevant when companies use neural or biometric signals to infer consumer preferences or emotions.

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[327] See par. 3.4.2

[328] OECD, *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (OECD 2013).

[329] Council of Europe, *Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data (Convention 108+)*, ETS No 223 (adopted 10 October 2018; consolidated text).

[330] OECD, *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (2013): Paragraph 7 (Collection Limitation Principle) requires data to be obtained by lawful and fair means and, where appropriate, with the knowledge or consent of the data subject; paragraph 9 (Purpose Specification Principle) requires that the purposes for which data are collected be specified no later than at the time of collection; paragraph 10 (Use Limitation Principle) limits the use of personal data to the specified purposes, unless further use is authorised by law or consented to by the data subject.

In addition to formal regulation, the neuromarketing industry is also subject to self-regulatory initiatives developed by sectoral organizations. The European Society for Opinion and Marketing Research (ESOMAR) published a set of practical guidelines in 2011[331] intended to assist companies and researchers in understanding what questions to ask when commissioning or conducting neuroscience-based research. These guidelines are not legally binding, but they aim to promote responsible data collection, participant protection, and methodological transparency in the application of neuroscience to commercial research.

Likewise, the Neuromarketing Science and Business Association (NMSBA) issued a Code of Ethics in 2013 to govern the use of neuroscience in business contexts. The code sets out standards on issues such as informed consent, participant safety, and data integrity[332]. However, the scope of the NMSBA code is limited to its member companies and does not carry formal legal weight. As such, while these initiatives contribute to shaping industry best practices, their enforcement relies on voluntary compliance rather than legal obligation.

3.4.2 Regulatory gaps in neuromarketing

The growing use of neurotechnologies raises serious legal and ethical concerns when applied in commercial settings such as neuromarketing. These technologies, while potentially beneficial for understanding human behavior or improving health outcomes, can also be used to subtly manipulate consumer choices in ways that undermine individual autonomy and mental privacy. The current regulatory framework, though built on robust instruments like the General Data Protection Regulation (GDPR), the Digital Services

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[331] In 2012, ESOMAR released a white paper titled *36 Questions to Help Commission Neuroscience Research*. The document guides organizations in choosing appropriate neuroscience-based tools for marketing research, covering aspects such as technique selection, sample validity, data quality, metrics, compliance, and ethical practices, all of which are crucial when employing methods like EEG, eye-tracking, facial coding, and fMRI to infer consumer emotions and preferences: ESOMAR, *36 Questions to Help Commission Neuroscience Research* (ESOMAR 2011) https://ana.esomar.org/documents/36-questions-to-help-commission-neuroscience-research- accessed 14 July 2025.

[332] Neuromarketing Science and Business Association (NMSBA), *Code of Ethics* (2013) https://www.nmsba.com/neuromarketing-companies/code-of-ethics accessed 14 July 2025. The Code outlines ethical standards for the application of neuroscience in business contexts, including requirements for informed consent (art 5), participant safety and avoidance of harm (art 2), and data integrity and privacy protections (art 6).

Act (DSA), and the Artificial Intelligence Act (AI Act), appears fragmented and insufficient to address the specific challenges posed by such invasive techniques.

A fundamental issue is the inadequacy of consent as a basis for processing brain-derived data. Although the GDPR requires that consent be free, specific, informed, and unambiguous[333], its actual validity is doubtful when applied to complex data-processing operations involving neural data. In this sense, there is 'the difficulty of considering the consent obtained through the use of such practices as truly informed'[334]. The very nature of neural data compromises the data subject's ability to understand what they are consenting to.

The lack of foresight is further exacerbated by the legal system's failure to adequately classify and regulate inferred data. As noted by Sposini, 'inferred data is currently neither included among the particularly sensitive data under Article 9 of the GDPR nor in any other provision or recital, with the consequence that the entire European regulation may not apply'[335]. This regulatory gap raises the risk of unlawful use of brain-derived data and insufficient safeguards for mental integrity.

The AI Act also reveals significant limitations in addressing the risks posed by neuromarketing. Its current framework excludes many neuromarketing practices from stricter regulation, as it only targets manipulative AI likely to cause physical or psychological harm. This narrow focus creates a loophole, leaving ethically questionable but non-harmful techniques largely unregulated. In fact, 'not every neuromarketing practice can be said to be subliminal and manipulative per se because otherwise, the entire discipline would be illegitimate'[336].

Another critical issue with the AI Act lies in its reliance on transparency obligations that are often vague and insufficient. Article 50 requires AI systems designed to interact with humans to inform users that they are dealing with an AI, 'unless this is obvious from the point of view of a natural person who is reasonably well-informed, observant and circumspect'[337]. However, the notion of what is "obvious" remains unclear, and the

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[333] See n 312.

[334] Ilaria Garaci, 'Neuromarketing e soggetti vulnerabili' in Salvatore Orlando (ed), *Profili giuridici del neuromarketing. Annuario 2023–2024 OGID Osservatorio Giuridico sull'Innovazione Digitale* (Sapienza Università Editrice 2025)135 (author's translation).

[335] Ludovica Sposini, 'Neuromarketing and Eye-Tracking Technologies Under the European Framework: Towards the GDPR and Beyond' (2024) 47 *Journal of Consumer Policy* 329.

[336] ibid, 338.

[337] AI Act, art. 50 (1).

responsibility for assessing this “obviousness” is ambiguously placed on the AI system itself, not been clear at the same time ‘how the AI system is supposed to assess this “obviousness”’[338]. This ambiguity risks undermining user awareness and weakens protections, especially in subtle contexts like neuromarketing, where influence often operates below conscious recognition.

Moreover, the Digital Services Act presents significant limitations in effectively regulating algorithmic advertising practices. Article 26 (3) prohibits targeted ads based on special categories of personal data, such as biometric or health data under Article 9 of the GDPR. However, this prohibition is practically difficult to enforce due to ‘the complexity of algorithmic mechanisms and the immense volume of data analyzed’[339], which makes it hard to detect the indirect or unintended use of sensitive data by autonomous systems trained for profit maximization. Moreover, the DSA’s scope is narrowly confined to ‘online platform providers’[340] thereby excluding other actors who might engage in similar profiling practices. This restricted applicability significantly weakens the potential of the DSA to address the broader risks associated with manipulative or discriminatory advertising strategies.

As examined so far, existing regulatory instruments like the GDPR, the DSA, and the AI Act provide important safeguards, yet they remain insufficient to fully address the complex and evolving challenges posed by neuromarketing and neurotechnologies. This regulatory incompleteness calls for a more targeted and forward-looking approach.

3.4.3. Proposals for future regulation

As seen in the previous section, neurotechnology continues to evolve and intersect with marketing, data analytics, and digital services; at the same time, the current regulatory frameworks, while robust in some respects, reveal significant gaps in protecting

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[338] Valentina Vincenza Cuocci, ‘Persone vulnerabili e scelte (in)consapevoli: riflessioni su neuromarketing e protezione dei dati personali nell’era dell’intelligenza artificiale’ in Salvatore Orlando (ed), *Profili giuridici del neuromarketing. Annuario 2023–2024 OGID Osservatorio Giuridico sull’Innovazione Digitale* (Sapienza Università Editrice 2025)72 (author’s translation).

[339] Beniamino Parenzo, ‘Neuromarketing: un inventario di (spuntati) divieti contro il pericolo di una scelta manipolata’ in Salvatore Orlando (ed), *Profili giuridici del neuromarketing. Annuario 2023–2024 OGID Osservatorio Giuridico sull’Innovazione Digitale* (Sapienza Università Editrice 2025) 268 (author’s translation).

[340] ibid (author’s translation).

individuals' cognitive autonomy and mental privacy. The use of neurodata, particularly when combined with AI and profiling techniques, raises pressing ethical and legal challenges that existing laws are only partially equipped to address.

A desirable regulatory development would be to expand the current provisions of the General Data Protection Regulation (GDPR) to explicitly include inferred data among the categories of sensitive personal data. Inferred neurodata, such as mental states, cognitive load, or emotional responses, are increasingly derived from indirect signals like gaze direction, EEG patterns, or behavioral cues. Despite their indirect nature, such data can reveal deeply intimate aspects of an individual's mental life and should therefore enjoy the same level of protection as biometric or health data under Article 9 of the GDPR. Incorporating inferred data would close a critical gap in the legal framework, recognizing the growing predictive and persuasive power of these signals in neuromarketing and anticipatory commerce.

However, even such an inclusion would not resolve a second, more structural concern: the fragility of consent as a legal basis for processing neurodata. Under current EU data protection law, valid consent must meet strict criteria[341]. Yet, in practice, this standard is often unmet in neuromarketing contexts. The complexity of neural data processing, its opacity to the average user, and the hidden nature of persuasive influence severely compromise the user's ability to give truly informed consent. Therefore, it becomes necessary to rethink consent mechanisms, particularly through the introduction of a *cognitive informed consent* framework. This would involve a prior assessment of the individual's ability to understand the implications of neurodata processing, a mandatory explanation of potential manipulative or affective effects, and real-time opt-out systems that allow the user to revoke consent at any moment, especially in contexts where neural data may be used to generate behavioral nudges or automated decisions.

Not all scholars agree with this approach. Some argue that regulating the processing of mental data itself may be less effective than a more pragmatic, device-focused approach. Some argue that, 'the human right to mental privacy remains aspirational'[342] and therefore 'the only conceivable way of curbing [neuromarketing's] negative effects is

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[341] See n 312.

[342] Alexander Sieber, 'Souled out of rights? – Predicaments in protecting the human spirit in the age of neuromarketing' (2019) 15 *Life Sciences, Society and Policy* 10.

through regulation of the devices themselves'[343]. This view suggests that rather than aiming for broad and abstract rights-based protections, the law should focus on certifying, restricting, or banning certain types of neurotechnological devices, especially those used in commercial settings.

Nonetheless, regardless of which path is chosen, whether data-based or device-based, there is a strong case for extending legal protections to vulnerable populations beyond minors, who are currently the main focus of both the GDPR and the Digital Services Act (DSA). Elderly individuals, people with cognitive impairments, and other vulnerable groups are often excluded from enhanced protection mechanisms, despite being equally, if not more, susceptible to subtle forms of neuromarketing influence. Legislative reforms should amend the relevant provisions to explicitly include such populations, mandate enhanced consent verification procedures, and require psychological safeguards when targeting or collecting neurodata from vulnerable individuals.

In addition, the establishment of a dedicated regulatory authority for neuromarketing could offer a more coherent and proactive oversight mechanism. Such an authority would be empowered to monitor both private actors and public institutions, ensuring compliance with evolving neuroethical standards. Its role would be essential in countering undue influence not only from corporations capable of large-scale consumer manipulation, but also from states that may be tempted to use neurotechnologies for subtle behavioral control or surveillance purposes in a manner similar to the independent supervisory authorities provided for under the GDPR[344].

Looking ahead, one further protective measure that should be seriously considered is the recognition of a *right to neuro-digital disconnection*. As neurotechnology becomes increasingly embedded in everyday life, through smart assistants, wearable BCIs, or home-integrated systems, the possibility of opting out of such environments is rapidly diminishing. A legal right to disconnection would guarantee individuals the ability to deactivate all neural or predictive devices, enjoy a neutral digital environment free from neuro-persuasion, and be protected against invasive default settings. In a world where neural attention can trigger anticipatory shipping or personalized ads in real time, maintaining a space for autonomous, uninterrupted thought may be one of the most

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[343] ibid 8.

[344] See GDPR art 51, which requires each Member State to establish an independent public authority responsible for monitoring the application of the Regulation.

fundamental rights we will need to defend. Such a right would represent the technological realization, within the digital and cognitive sphere, of the historical “right to be let alone” articulated by Warren and Brandeis[345], reaffirming the individual’s entitlement to mental and emotional sovereignty in the face of pervasive and predictive systems.

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[345] See n 144.

Chapter 4: Protection of Neurorights and Neural Information

4.1 The GDPR and the protection of neurodata

4.1.1 Applicability of the GDPR to neurodata

The applicability of the General Data Protection Regulation (GDPR) to neurodata presents complex legal challenges that must be assessed both formally and substantively. Neurodata, understood as data derived from the monitoring and processing of neural activity, inherently relate to an identified or identifiable natural person, meeting the definition of personal data under Article 4(1) GDPR[346]. These data, extracted from devices such as EEGs, fMRIs, or BCIs, often reveal distinctive and individual neural signatures that are not only traceable to a specific person but can also express aspects of their cognitive identity. Their potential to disclose intimate information, such as emotions, intentions, memory traces, and mental predispositions, confers upon them an exceptional sensitivity that exceeds that of conventional personal data.

While their classification as personal data appears clear, their inclusion in the category of special data under Article 9 GDPR[347] is less straightforward. The Regulation grants heightened protection to data revealing racial or ethnic origin, political opinions, religious beliefs, genetic or biometric data, health data, and data concerning sexual life or orientation. Neurodata, however, do not always fall explicitly within these predefined categories, despite their capacity to infer equally (if not more) sensitive information. As emphasized by both the European Data Protection Supervisor (EDPS)[348] and the UK Information Commissioner's Office (ICO)[349], the involuntary nature of neurodata,

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[346] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation) [2016] OJ L119/1, art 4(1). Defines 'personal data' as 'any information relating to an identified or identifiable natural person'.

[347] GDPR art 9(1). Provides that 'special categories of personal data' include data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as genetic, biometric and health data.

[348] See European Data Protection Supervisor, *TechDispatch 2/2023: Brain-Computer Interfaces* (2024) https://edps.europa.eu/data-protection/our-work/publications/techdispatch/techdispatch-22023-brain-computer-interfaces_en. 4. The EDPS underlines that neurodata include inferences about emotions, intentions, and preferences, and warns that they can intrude upon the most intimate dimensions of identity.

[349] See Information Commissioner's Office, *Tech Futures: Neurotechnology* (2023) https://ico.org.uk/about-the-ico/what-we-do/tech-futures/neurotechnology/ (accessed 26 July 2025). The

generated subconsciously and without deliberate intention, renders them uniquely intrusive and ethically problematic. This lack of volitional control calls into question the adequacy of traditional consent mechanisms and demands regulatory adaptation.

The sensitive nature of neurodata is further confirmed when considering their possible inclusion under the notion of biometric data as defined in Article 4(14) GDPR[350]. In cases where neural signals are processed through technical means that allow the identification or authentication of a person, such as through characteristic patterns of brain activity, the neurodata may effectively serve as biometric identifiers. Scientific studies have shown that even brief recordings of brain activity can be sufficient to re-identify individuals with significant accuracy. This reinforces the notion that neurodata, like fingerprints or retinal scans, can possess identifying features that warrant enhanced legal protection.

Moreover, some neurodata might also border the legal domain of genetic data under Article 4(13) GDPR[351]. Although neurodata do not originate from DNA analysis, they can reveal inherited or acquired physiological traits that are correlated with genetic predispositions. The convergence of neural and genetic information, particularly in advanced neuroimaging and predictive applications, further blurs the boundaries between traditional data categories. This hybrid nature calls for an interpretative effort that aligns legal classifications with the technological reality of data processing.

Context plays a decisive role in determining the level of protection that neurodata require. According to GDPR principles[352] and EDPB guidelines[353], data may acquire sensitive status not only due to their intrinsic content but also as a result of their purpose or use. The same neural signal, when used for medical diagnosis, educational profiling, or

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ICO highlights that neurodata are generated subconsciously, without the data subject's awareness or control, raising serious issues for consent and mental privacy.

[350] GDPR art 4(14). Biometric data are defined as 'personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person' that allow identification.

[351] GDPR art 4(13). Genetic data are defined as 'personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person'.

[352] GDPR art 5. Sets out the core data protection principles, including purpose limitation, data minimisation, and integrity and confidentiality, which guide the contextual interpretation of what constitutes sensitive or protected data.

[353] See European Data Protection Board, *Guidelines 03/2020 on the Processing of Data Concerning Health for the Purpose of Scientific Research in the Context of the COVID-19 Outbreak* (21 April 2020) https://www.edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_en.pdfaccessed 18 July 2025, 5. The guidelines highlight that even data not intrinsically sensitive can become so depending on the purpose and context of processing.

behavioral prediction, can trigger different legal and ethical obligations. In the context of neurotechnology, this contextual sensitivity becomes particularly relevant, as the purposes of data processing often involve predictive or inferential operations that pose elevated risks to mental privacy and personal autonomy.

The conceptual and normative ambiguity surrounding the treatment of neurodata highlights the tension between existing legal categories and emerging technological phenomena. Although the GDPR provides foundational protection principles, the unique features of neurodata, such as their biological distinctiveness, inferential capacity, and predictive power, challenge the sufficiency of current frameworks. Their inclusion within the GDPR is, in principle, feasible, but requires a dynamic and functional interpretation of legal definitions that can respond to evolving technological contexts.

This situation raises concerns about the risk of regulatory grey areas, where the lack of explicit recognition of neurodata's specificity might undermine the effective protection of cognitive and mental integrity. In light of this, scholars and regulators increasingly call for a more nuanced approach that recognizes neurodata as a distinct and highly sensitive data category, warranting dedicated safeguards to ensure the protection of the most intimate sphere of human identity.

4.1.2 Limitations of the GDPR in the protection of neural information

Although the GDPR is one of the most advanced legal instruments for the protection of personal data, it shows systemic deficiencies when applied to information derived directly from brain or mental activity. Neurodata are often generated passively, involuntarily, and unintentionally by the data subject, who lacks awareness and control over the type of information being extracted and processed. This complicates reliance on free, specific, and informed consent as required by Articles 6 and 9 of the GDPR[354], thus undermining one of the fundamental pillars of lawful processing.

A second problem concerns the transparency and accessibility of information regarding processing. Neural decoding techniques are often opaque, based on machine learning

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[354] GDPR arts 6 and 9. Art 6 establishes the lawful bases for processing, including consent, while art 9 imposes stricter conditions for processing special categories of personal data, including data concerning health and biometric identifiers. Neurodata challenge both provisions due to the involuntary nature of their collection.

algorithms, and difficult to interpret even for the developers themselves. This creates a significant risk of *black box* decision-making, where the data subject cannot understand how their data is being used nor effectively exercise their rights of access, rectification, or objection[355].

The purpose limitation principle (Article 5(1)(b))[356] is also challenged, as neurodata, once collected, can be reused for multiple purposes due to their inferential and predictive power. Unlike other personal data, the informational content of neurodata is potentially unlimited and can be retroactively reinterpreted in light of new technologies or contexts. Finally, the GDPR appears poorly equipped to handle the new emerging rights in the bioethical and legal debate, such as mental privacy, psychological continuity, and cognitive liberty, all articulated within the framework of so-called neurorights. These rights, though conceptually related to existing fundamental rights (dignity, mental integrity, freedom of thought), still lack explicit formalization in the European legal framework, leaving regulatory gaps that can compromise the effective protection of the inner forum.

4.1.3 Proposals for integrating the GDPR

In light of the critical issues analyzed, a multi-level intervention is necessary to strengthen the protection of neurodata. Three main directions can be identified. First, a systematic interpretation of the GDPR in light of the Charter of Fundamental Rights of the European Union: provisions such as Article 1 (human dignity), Article 3 (physical and mental integrity), Article 7 (respect for private life), and Article 8 (data protection) must be read in an evolutionary key to include new vulnerabilities arising from the use of neurotechnologies[357].

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[355] GDPR arts 12–15 and 21. These articles guarantee transparency and data subject rights such as access, rectification, erasure, and the right to object. The opacity of algorithmic processing may render these rights ineffective in practice when applied to neurodata.

[356] GDPR art 5(1)(b). This article provides that personal data must be 'collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes' (purpose limitation). The predictive potential of neurodata often undermines this principle through secondary or retrospective uses.

[357] Charter of Fundamental Rights of the European Union [2012] OJ C326/391, arts 1, 3, 7, and 8. These provisions protect human dignity, physical and mental integrity, respect for private and family life, and the right to personal data protection. Their interpretation may evolve in response to neurotechnological risks.

Second, data protection authorities (such as EDPS and EDPB) could develop specific guidelines for the processing of neurodata, inspired by a contextual and proportional approach. In this sense, an interpretative doctrine could be adopted that treats neurodata as "contextually highly sensitive data," whose legal classification should depend on use, potential risk, and the power structure within the relationship between data subject and controller.

Finally, the possibility (if not the necessity) of a regulatory intervention aimed at formally recognizing neurodata as a legal category deserving of enhanced safeguards cannot be excluded. This does not necessarily imply the adoption of new legislative texts, as part of the doctrine has proposed, but could be achieved through an interpretative evolution or integration of existing legal instruments, such as the GDPR itself or secondary EU legislation[358]. Such reform could take the form of a complementary regulation to the GDPR or a specific directive on the processing of neural and mental data, similar to what has already occurred in the field of genetic or biometric data.

This reform will also have to confront the ongoing debate on the risk of inflation of fundamental rights. Some scholars, such as Bublitz[359] and Hertz[360], argue that there is no need for new rights, but rather a reconceptualization of existing ones. However, the intensity of the challenges posed by neurocapitalism and new forms of cognitive surveillance suggests that the legal system must also evolve at the axiological level, recognizing the mind as the new frontier in the protection of fundamental rights.

4.2 Proposals for a sectoral regulatory framework

4.2.1 Specific regulations for the healthcare sector

In the healthcare sector, the regulation of neural data can already rely on a relatively structured legal framework, particularly thanks to the enhanced protection offered by the GDPR. Article 9 of the regulation, in principle, prohibits the processing of health-related

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[358] See also Recitals 10 and 53 GDPR, which foresee the possibility of sector-specific rules or further protective measures under Union law for certain categories of data, including biometric or genetic data.

[359] See Jan Christoph Bublitz, 'Novel Neurorights: From Nonsense to Substance' (2022) 16 *Neuroethics* 15.

[360] See Nora Hertz, 'Neurorights – Do We Need New Human Rights? A Reconsideration of the Right to Freedom of Thought' (2023) 16 *Neuroethics* 5, 4.

data unless specific conditions and safeguards are met, such as the data subject's explicit consent or the necessity of the processing for purposes of diagnosis, care, or healthcare management[361]. In this perspective, neural data collected in clinical contexts, such as through neuroimaging technologies or neurostimulation devices, can generally be classified as sensitive data, and thus benefit from reinforced legal protection[362].

However, the picture becomes more complex when one considers the inferential nature of neural data. Unlike traditional health data, neural data may not be immediately informative: its meaning is constructed through a series of algorithmic elaborations, which often extract predictive, emotional, or cognitive elements that are not explicitly expressed by the subject[363]. In this sense, neural data can shift, depending on the context and purpose of processing, into a form of metadata that escapes the immediate classification as health data, even though it is logically derived from it. For example, an EEG signal recorded in a clinical setting might, if reinterpreted in a non-medical context (e.g., for commercial or behavioral purposes), fall outside the protective scope of Article 9 GDPR, entering a grey area of inferred personal data processing. This semantic slippage between contexts highlights the urgent need for a more nuanced legal reflection on the nature and life cycle of neural data.

Moreover, the growing use of artificial intelligence in clinical and diagnostic devices introduces further regulatory challenges. Machine learning algorithms used to interpret neural signals and produce pathological predictions often operate in an opaque (black box) mode, making it difficult to identify the decision logic and, consequently, to assess the accuracy and proportionality of the processing. In this context, the recently adopted EU Artificial Intelligence Act (AI Act) classifies as high-risk those AI systems intended to determine access to essential public services, including healthcare, as specified

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[361] GDPR art 9. The article explains the general prohibition on processing health data and the strict exceptions under which it becomes lawful.

[362] See also EDPB *Guidelines 03/2020* (n 353). The document clarifies that data not originally classified as health-related can become such depending on context and purpose.

[363] See EDPS *TechDispatch 2024/01* (n 348); and Ludovica Sposini, 'Neuromarketing and Eye Tracking Technologies Under the European Framework: Towards the GDPR and Beyond' (2024) 47 *Journal of Consumer Policy* 329. The EDPS introduces the concept of neurodata as often inferred and context-sensitive, deserving heightened regulatory attention. Sposini discusses the legal classification of inferred data under the GDPR, highlighting their potential inclusion within the scope of personal or sensitive data depending on purpose and effect.

in Annex III, point 5[364]. This classification imposes strict obligations on providers and deployers concerning transparency, data quality, human oversight, and risk management. At the same time, the AI Act acknowledges that existing sectoral legislation may be insufficient to fully address the specific risks posed by AI technologies in healthcare. As recital 50 clarifies:

> medical devices products incorporating an AI system might present risks not addressed by the essential health and safety requirements set out in the relevant Union harmonised legislation, as that sectoral law does not deal with risks specific to AI systems. This calls for a simultaneous and complementary application of the various legislative acts.[365]

This statement highlights the importance of a harmonised and integrated regulatory approach, capable of bridging gaps between data protection law, sector-specific regulation, and AI governance.

4.2.2 Regulation of neurotechnology across different sectors

Outside the healthcare sector, neurotechnologies are increasingly being applied in heterogeneous domains such as marketing[366], education[367], employment[368], or public security[369], often in the absence of a clear and specific regulatory framework. In these contexts, the use of devices capable of collecting, processing, and interpreting neurodata such as brain-computer interfaces, wearable EEGs, or neuromarketing technologies often relies on a generic qualification of the data as "personal," without acknowledging its

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[364] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 March 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts [2024] OJ L153/1, Annex III, para 5. Classifies as high-risk those AI systems intended to determine access to essential private or public services, including healthcare services.

[365] AI Act, recital 64.

[366] See chapter 3.

[367] See Javad Alipoor and Hatef Pourrashidi, ‘A Critical Study on the Researches about the Application of Neurotechnology in Education’ (2024) *International Journal of Neuroscience* 7.

[368] See Patrick D Hopkins and Harvey L Fiser, ‘“This Position Requires Some Alteration of Your Brain”: On the Moral and Legal Issues of Using Neurotechnology to Modify Employees’ (2017) 144 *Journal of Business Ethics* 783.

[369] See James Giordano (ed), *Neurotechnology in National Security and Defense: Practical Considerations, Neuroethical Concerns* (1st edn, CRC Press 2014).

intrinsic sensitivity or its connection to the intimate sphere of the mind. Unlike the clinical context, in fact, these domains do not automatically benefit from the safeguards foreseen for special categories of data under the GDPR, leaving a range of processing practices potentially harmful to cognitive autonomy and mental integrity without sufficient legal protection.

In this scenario, a dual-track regulatory strategy is essential. On the one hand, prompt sectoral intervention is needed to fill normative gaps in specific application areas. For instance, specific regulations could be introduced in the short term for consumer neurotechnologies, such as attention-training neurofeedback devices or cognitive stimulation apps, requiring minimum standards of transparency, safety, and scientific validation. In parallel, a dedicated framework could be developed for the workplace, prohibiting the use of neurotechnologies for surveillance or behavioral evaluation without free and informed consent.

On the other hand, in the medium to long term, there is a need to build a horizontal and cross-sectoral framework capable of offering consistent and uniform protection of neurorights across all domains of use. This general framework should be grounded on several fundamental principles: the explicit recognition of the traditional rights connected to neural data[370], such as cognitive liberty, mental privacy, mental integrity and psychological continuity; the legal definition of neurodata as an autonomous and highly sensitive category; and the introduction of contextual criteria to assess the lawfulness of processing, taking into account not only the nature of the data but also the purpose and context of its use. Such a model could be reinforced by international coordination, based on shared European and global guidelines, as already seen in the fields of biotechnology or artificial intelligence.

Ultimately, sectoral regulation should not be seen as an alternative to horizontal regulation but rather as a strategic first step toward a multilevel governance of neurotechnology. Only an integrated approach, capable of combining timely, targeted responses with progressive systemic harmonization, can ensure the effective protection of cognitive rights in the era of the connected mind.

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[370] See section 2.2.

4.3 European and international frameworks for neurotechnology regulation

4.3.1 European regulatory initiatives

The European Union has increasingly recognised the need to address the ethical, legal, and social implications of neurotechnologies. While no dedicated regulation currently exists, a growing number of initiatives, both institutional and policy-based, have begun to shape a distinct European approach to the governance of neurotechnological innovation. Having previously examined the legal protection of neural data within the European framework[371], the focus now shifts to regulatory initiatives more specifically aimed at the development and deployment of neurotechnological systems themselves.

A key step in this direction was the León Declaration on European Neurotechnology, adopted in 2023 under the Spanish Presidency of the Council of the EU. The declaration encourages Member States to initiate high-level dialogue on whether the current regulatory framework is sufficient to protect fundamental rights in light of the development of neurotechnologies[372]. This concern is echoed by the European Brain Council's Charter for the Responsible Development of Neurotechnologies, a soft-law instrument that sets out ethical and policy guidelines, calling for greater transparency in neurodata use, safeguards against commercial exploitation, and stronger public engagement[373].

Complementing these efforts, the TechEthos project, funded under Horizon Europe, has produced dedicated policy briefs identifying key priorities for neurotechnology governance. Among the recommendations are the recognition of neurorights, such as mental privacy and cognitive liberty, within the EU Charter of Fundamental Rights, a

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[371] See section 2.5.1.

[372] Spanish Presidency of the Council of the European Union, "León Declaration on European Neurotechnology: A Human-Centric and Rights-Oriented Approach" (Press Release, 24 October 2023) https://wayback.archive-it.org/12090/20240613112737/https://spanish-presidency.consilium.europa.eu/es/noticias/declaracion-leon-neurotecnologia-europea-ue-derechos-humanos/ accessed 26 July 2025.

[373] European Brain Council, *European Charter for the Responsible Development of Neurotechnologies* (Brussels, 28 April 2025)https://www.braincouncil.eu/wp-content/uploads/2025/04/European-Charter-for-the-Responsible-Development-of-NeuroTechnologies-FINAL.pdf accessed 26 July 2025.

clarification of the legal status of neural data under Article 9 GDPR, and the introduction of ethical impact assessments as part of future regulatory design[374].

At the institutional level, the European Parliament has played an active role through the Scientific and Technological Options Assessment (STOA) programme. In November 2023, it hosted a dedicated workshop titled *"Neurotechnology and Neurorights – Privacy's Last Frontier"*, which brought together legal scholars, ethicists, and policymakers to assess the adequacy of existing protections and explore the possibility of a normative framework for neurorights. The debate 'discussed the open issues and the future of neurorights, including the gaps in human rights legislation, solutions within the EU's privacy framework, including the AI Act'[375].

In addition, the European Parliamentary Research Service (EPRS) has issued a comprehensive policy study titled *"The protection of mental privacy in the area of neuroscience"*. The report evaluates whether existing rights, such as those enshrined in Article 3 of the Charter of Fundamental Rights of the European Union[376] and Article 8 of the European Convention on Human Rights[377], are sufficient to ensure protection from intrusions into the mind[378]. It also raises the question of whether emerging neurotechnologies may require reinterpretation or expansion of existing legal categories to address the novel risks posed by neural data processing.

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[374] See TechEthos Consortium, *Analysis of International and EU Law and Policy for Neurotechnologies* (TechEthos, Horizon Europe, July 2022) and *Enhancing EU Legal Frameworks for Neurotechnologies: Policy Brief* (TechEthos Policy Brief, February 2023) https://www.techethos.eu/wp-content/uploads/2022/08/TechEthos_D4.1-Intl-and-EU-legal-analysis_Part-II_Neurotechnologies.pdf and https://www.techethos.eu/wp-content/uploads/2023/03/TECHETHOS-POLICY-BRIEF_Neurotechnologies_for-web.pdf accessed 26 July 2025. The documents contain a detailed legal and policy analysis of international and EU frameworks relevant to neurotechnologies, and a policy brief with regulatory recommendations for protecting neural data, promoting neurorights, and embedding ethics-by-design in EU law.

[375] European Parliament, Panel for the Future of Science and Technology (STOA), *Annual Report 2023* (Scientific Foresight Unit, European Parliamentary Research Service, March 2024) PE 757.792, 12 https://www.europarl.europa.eu/cmsdata/283253/EPRS_STUD_757792_Annual_Report_2023_FINAL.pdf accessed 26 July 2025.

[376] Charter of Fundamental Rights of the European Union [2012] OJ C326/391, art 3: establishes the right to the integrity of the person, including respect for mental and physical integrity. It forms the normative basis for protections related to bodily and cognitive autonomy, relevant in the context of neurorights.

[377] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (adopted 4 November 1950, entered into force 3 September 1953) ETS No 5, art 8: protects the right to respect for private and family life.

[378] European Parliament, Panel for the Future of Science and Technology (STOA), *The Protection of Mental Privacy in the Area of Neuroscience – Societal, Legal and Ethical Challenges* (Scientific Foresight Unit, European Parliamentary Research Service EPRS, July 2024) PE 757.807, 31 https://www.europarl.europa.eu/RegData/etudes/STUD/2024/757807/EPRS_STU%282024%29757807_EN.pdf accessed 26 July 2025.

Taken together, these initiatives reveal a growing institutional awareness of the disruptive potential of neurotechnologies. Although there is not yet a unified regulatory framework, the EU is clearly laying the groundwork for a future regime that integrates ethical principles, neurorights, and data protection in a coherent, rights-based governance structure.

4.3.2 Global harmonization and international cooperation

As neurotechnologies rapidly transcend national borders, global harmonization becomes essential to ensure consistent protection of neurorights and harmonized governance standards. International organisations can play a pivotal role by developing shared frameworks, capacity-building tools, and multi-stakeholder platforms tailored to the unique challenges of neurotechnology regulation.

Building on the OECD Recommendation on Responsible Innovation in Neurotechnology[379], member states are encouraged to align domestic regulation with guiding principles that balance technological innovation, human dignity, and mental privacy. This instrument offers a concrete policy baseline that can inform global regulatory convergence without imposing binding legal norms.

Meanwhile, UNESCO's forthcoming "Recommendation on the Ethics of Neurotechnology" (expected to be adopted at the 43rd General Conference in late 2025) proposes a comprehensive architecture for ethical governance, including: an Ethical Impact Assessment methodology for neurotechnology across its lifecycle; a global observatory for best practice and data-driven policy analysis; and a Ministerial-level Global Forum platform with expert networks to foster sustained dialogue[380].

These UNESCO tools aim to support national governments in implementing shared values (like mental integrity, cognitive liberty, non-manipulation), and offer technical guidance for ethical and legal oversight. They also address the need for cross-sectoral cooperation among states, researchers, industry, and civil society actors.

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[379] OECD, Recommendation of the Council on Responsible Innovation in Neurotechnology (OECD/LEGAL/0457, 2019).

[380] UNESCO International Bioethics Committee (IBC), *Final Report of the Draft Recommendation on the Ethics of Neurotechnology* (UNESCO, first published as draft in 2024; finalisation expected November 2025) https://unesdoc.unesco.org/ark:/48223/pf0000393266 accessed 26 July 2025.

However, to translate soft-law principles into effective global standards, institutional mechanisms are required. For instance, creating a multilateral certification process (analogous to organizations like the Global Partnership on AI[381]) could ensure consistent implementation of neurotechnology norms across jurisdictions. Such instruments could be administered by international bodies (e.g. UNESCO, OECD, Council of Europe), in collaboration with regional regulators like the European Commission.

Ultimately, global harmonization hinges on building institutional bridges: multi-layered, inclusive, legally coherent frameworks that safeguard neural data and human autonomy. Through coordination by international organisations, harmonized policies and harmonized oversight can reduce fragmentation, prevent regulatory gaps, and ensure consistent resilience across jurisdictions.

4.4 Governance strategies for neurotechnology

4.4.1 Multilevel governance

The regulation of neurotechnologies and neurodata cannot be effectively addressed within the confines of national legal systems alone. Their hybrid nature, which intersects health law, data protection, human rights, and technological governance, calls for approaches capable of reflecting the complexity of their development and use. The concept of multilevel governance, originally elaborated within political science to describe the European Union's institutional architecture[382], has become a useful paradigm for understanding how authority and regulation can be dispersed and shared across different institutional levels. Rather than a rigid, top-down system, multilevel governance envisages overlapping competencies, constant negotiation, and cooperative interaction between authorities.

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[381] Global Partnership on Artificial Intelligence (GPAI), *About GPAI* https://www.gpai.ai/about/ accessed 26 July 2025. An international multistakeholder initiative launched in 2020 to promote the responsible development and use of artificial intelligence in accordance with human rights, democratic values, and the OECD AI Principles. GPAI serves as a forum for global cooperation and policy coordination on AI governance.

[382] Gary Marks and Liesbet Hooghe, 'Contrasting Visions of Multi-Level Governance' (2004) 6 *Multi-level Governance* 15.

In the context of neurotechnology, this perspective becomes particularly relevant. At the national level, states remain the primary guarantors of fundamental rights, with legislatures and courts responsible for delineating the scope of privacy, mental integrity, and freedom of thought. National health authorities, moreover, regulate medical devices and research standards, directly shaping how these technologies are deployed in clinical and commercial contexts. Supranational frameworks, such as the European Union, provide another crucial layer. The General Data Protection Regulation already establishes a robust system for sensitive data, but the emergence of neurodata, potentially capable of revealing cognitive states, predispositions, or emotional patterns, raises challenges that stretch the existing provisions. Coordinated action at this level could reduce regulatory fragmentation and facilitate trust in cross-border applications of neurotechnologies. At the global level, the inherently transnational circulation of devices and software requires common principles. International institutions such as UNESCO and the OECD have already articulated ethical frameworks for artificial intelligence and responsible innovation[383], and similar initiatives could be extended to neurotechnologies to prevent regulatory havens and secure a minimum set of shared guarantees.

The advantage of such a multilevel architecture is that it mirrors the technological reality itself: neurotechnologies are developed by global corporations, tested and approved within national health systems, and debated in international fora. Governance that reflects this dispersion of authority allows for harmonization, cross-learning, and mutual recognition across borders. Yet the model is not without challenges. Divergences between cultural and legal traditions may complicate the global recognition of neuro-rights, and overlapping competences can produce conflicts of jurisdiction or even regulatory vacuums. To function effectively, multilevel governance requires robust mechanisms of coordination, ranging from joint regulatory platforms to transnational databases and mutual recognition schemes.

4.4.2 Participatory regulation models

If multilevel governance addresses the vertical distribution of authority, participatory regulation focuses on the horizontal inclusion of actors in the creation, implementation,

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[383] See section 2.4.

and revision of rules. This approach represents a significant departure from the traditional command-and-control model of regulation, as it seeks to integrate the perspectives of citizens, patients, researchers, civil society organizations, and industry representatives into the regulatory process. Its theoretical roots can be found in the broader field of democratic theory and regulatory governance, where authors such as Archon Fung and Erik Olin Wright[384] have emphasized the importance of institutional designs that allow communities directly affected by decisions to participate in shaping them.

In the field of neurotechnology, the participatory dimension acquires particular significance. Neurodata, unlike other categories of personal data, may disclose intimate aspects of identity, thought, or emotional life. The legitimacy of decisions concerning their collection and use cannot therefore rest exclusively on the authority of experts or on market practices. Instead, rules that emerge from participatory processes are likely to gain broader democratic legitimacy, as they incorporate diverse perspectives and address ethical concerns that may otherwise remain invisible. By widening the range of actors who can intervene, participatory models also reduce the risk of regulatory capture, ensuring that regulatory frameworks are not disproportionately influenced by the interests of powerful corporations or research consortia[385].

The implementation of participatory regulation in practice can take different forms, ranging from consultative exercises to institutionalized deliberative platforms. Public consultations can be used to gather input from a broad audience on proposed laws or technical standards, while ethics committees and advisory boards may be designed with mixed membership that includes not only experts but also patient representatives and lay citizens. Digital deliberation platforms, inspired by experiences such as vTaiwan[386] or Decidim[387], illustrate how technology itself can be used to foster discussion and collective refinement of proposals. Even the monitoring phase of regulation can be designed

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[384] Archon Fung and Erik Olin Wright, ‘Deepening Democracy: Innovations in Empowered Participatory Governance’ (2001) 29 *Politics and Society* 5

[385] See Hanan Haber and Eva Maria Heims, ‘Regulating with the Masses? Mapping the Spread of Participatory Regulation’ (2020) *Journal of European Public Policy* 27(12), 1742.

[386] vTaiwan is a digital consultation process launched in Taiwan in 2014 that combines online deliberation with face-to-face meetings, enabling citizens, experts, and government representatives to co-create policies on issues such as regulation of digital platforms. See https://info.vtaiwan.tw accessed 21 August 2025.

[387] Decidim is an open-source participatory democracy platform first developed in Barcelona, allowing citizens to propose, debate, and vote on policies, budgets, and regulations at the municipal and institutional level. See https://decidim.org accessed 21 August 2025.

participatively, for example through citizen auditing of compliance with ethical standards in research or clinical practice.

These models, however, must address several difficulties. Participation can be time-consuming and resource-intensive, and there is always the risk that it degenerates into tokenism[388], with citizens formally consulted but with little real influence on final decisions. The technical complexity of neurotechnologies further complicates the process, since participants must be placed in a position to understand the issues and contribute meaningfully. For participatory regulation to be more than a symbolic exercise, significant investments in capacity-building, transparency, and feedback mechanisms are required.

In the governance of neurotechnologies, participatory regulation should not be conceived as a substitute for legal frameworks but as their complement. Traditional regulatory instruments remain essential to enforce rights and obligations, but they can be enriched by processes that bring in the perspectives of those most affected. In an area where ethical and social implications are at least as important as technical safety, participatory approaches provide a necessary counterweight to technocratic expertise and ensure that governance reflects shared societal values.

4.5 Future perspectives: what kind of regulation is needed?

4.5.1 From top-down lawmaking to participatory regulation by technology

Traditional regulatory frameworks have long relied on a top-down logic, whereby legislatures or regulatory authorities draft rules in advance and impose them on market actors. While effective in some contexts, this model struggles to keep pace with technological innovation, which evolves rapidly, often unpredictably, and in ways that outstrip the capacity of formal legal systems. As Bassan has convincingly argued in relation to digital platforms and blockchain[389], the rigidity of traditional norm-making

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[388] Tokenism refers to the superficial or symbolic inclusion of individuals or groups in decision-making processes, giving an appearance of participation without granting them any real influence over outcomes.

[389] Fabio Bassan, 'Digital Platforms and Blockchains: The Age of Participated Regulation' (European Business Law Review, forthcoming, 10 October 2022) https://ssrn.com/abstract=4244139 accessed 21 August 2025.

risks producing a constant misalignment between law and technological practice. The outcome is either over-regulation, which suffocates innovation, or under-regulation, which leaves critical areas of risk unaddressed.

Bassan's proposed model of *participatory regulation by technology* suggests an alternative regulatory cycle based on interaction between technological practices and regulatory authorities. In its four phases, innovation begins with the spontaneous formation of market practices, which are then observed and selectively translated into benchmarks by public authorities. These benchmarks may in turn be formalised through soft law instruments, delegated acts, or legislation, before being incorporated directly into the technological systems themselves. In this way, compliance is not imposed from outside but becomes internalised in protocols, algorithms, and code.

While Bassan's focus is on digital platforms and blockchain, the logic of his approach resonates strongly with the challenges of regulating neurotechnologies. If adapted to this field, such a model could allow governance to evolve more dynamically, in constant dialogue with technological innovation, while reducing the time lag between emerging risks and regulatory responses. Importantly, this should not be seen as the exclusive or definitive approach to the problem, but rather as one possible framework that can complement, rather than replace, more traditional legal instruments.

4.5.2 The challenge of technological opacity and the need for auditability

One of the main obstacles to applying Bassan's cycle to neurotechnologies lies in the opacity of the systems themselves. Many devices rely on deep neural networks or advanced forms of machine learning that are, by their nature, not easily interpretable. If regulation is to be embedded directly into such systems, then the rules risk becoming invisible and unverifiable. As Bassan observes in relation to blockchain protocols, incorporation into technology can make rules extremely effective in terms of enforcement, but only on condition that compliance remains intelligible and subject to oversight. Without transparency, incorporation risks degenerating into mere technical ritual, undermining the very purpose of regulation.

For neurotechnologies, this challenge is even more pressing. Devices that read, stimulate, or infer neural states generate forms of neurodata whose processing may be inaccessible even to their developers. To respond to this, one possible adaptation of Bassan's model could be the principle of *auditability by design*[390]. This would entail building explainability and traceability into systems from the outset, so that embedded rules can be subject to external verification. Mechanisms such as neural registries of system activity, documenting access and stimulation, would allow regulators, independent auditors, and potentially even users themselves to verify whether legal standards are respected.

Of course, this is not the only possible response to technological opacity. Other strategies may include the imposition of certification requirements, mandatory third-party testing, or liability regimes designed specifically for "black box" technologies. Nevertheless, the core point remains: if the participatory regulatory cycle is to function meaningfully in the neurotechnology field, opacity must be mitigated by ensuring that embedded rules are not only present but also observable and verifiable.

4.5.3 Balancing asymmetries between public and private actors

Another challenge in adapting Bassan's model to neurotechnologies concerns the asymmetry of knowledge and power between public authorities and private actors. In his analysis of digital platforms, Bassan highlights the difficulty of ensuring that regulatory benchmarks emerge from a genuinely participatory process rather than from unilateral practices dictated by dominant market players. This risk is magnified in the neurotechnology domain, where regulatory bodies often lack the neuroscientific, engineering, and computational expertise required to evaluate technological practices critically.

If regulatory agencies merely observe and ratify industry-generated practices, the participatory model risks collapsing into a sophisticated form of self-regulation. One way to counter this is to create hybrid oversight bodies composed of jurists, neuroscientists, engineers, ethicists, and representatives of civil society. These entities could function as multidisciplinary regulators, capable of interpreting market practices, assessing their

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[390] The principle of "auditability by design" refers to the integration of mechanisms of transparency, traceability, and verifiability within technological systems from the outset, ensuring that processes, decisions, and embedded rules can be inspected and evaluated by regulators, auditors, or other stakeholders.

normative value, and translating them into benchmarks without being overpowered by private interests.

Alternative approaches might involve strengthening the technical expertise of existing agencies, developing advisory councils with broad membership, or fostering transnational collaborations where knowledge and resources are pooled. Whichever model is chosen, the key issue is to prevent asymmetry from undermining the legitimacy of the regulatory process. Without a genuine balance of expertise, the participatory cycle could be co-opted by private actors and lose its normative credibility.

4.5.4 The non-negotiable core of fundamental rights

Perhaps the most important adaptation of Bassan's model for the neurotechnology context is the recognition that certain rights are non-negotiable. Whereas practices in fields such as blockchain or digital platforms may be relatively malleable, the regulation of neurotechnologies implicates fundamental rights at the core of human dignity. Mental integrity, psychological continuity, freedom from manipulation, and cognitive liberty are not matters to be bargained away or gradually adjusted through regulatory experimentation.

This does not mean rejecting the participatory cycle, but it does mean anchoring it firmly in a framework of fundamental rights. As previously examined[391], scholars such as Marcello Ienca and Rafael Yuste have argued for the recognition of neurorights as guiding principles in this field, and their work provides a useful reference point for adapting the model. Rather than inventing entirely new regulatory instruments, it may be sufficient to update existing frameworks such as the GDPR, the AI Act, or international soft law instruments[392], ensuring that they explicitly cover neurodata and neurotechnologies. In this way, the participatory cycle can function dynamically while remaining bounded by non-negotiable normative commitments.

In light of these considerations, the proposal is not presented as the sole or definitive model for regulating neurotechnologies and neurodata, but rather as one possible approach among many. The challenges posed by neurotechnologies, ranging from

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[391] See section 2.2.

[392] See section 2.3.1.

technical opacity to asymmetries of expertise, and from rapid innovation to the protection of fundamental rights, are too complex to be resolved by a single framework. The participatory regulation by technology model, adapted to this field, offers a promising way of aligning governance with technological realities while safeguarding human dignity.

Yet the path forward will inevitably require dialogue and experimentation, since no single regulatory blueprint can fully anticipate the rapid evolution of neurotechnologies and the diverse contexts in which they are deployed. It is essential that institutions, citizens, and industry actors continue to engage with one another in a spirit of collective responsibility and continuous improvement, recognising that regulation in this domain cannot be a one-off exercise but must instead operate as an ongoing process of adaptation. Such engagement should not be limited to formal policymaking arenas, but should also include public deliberation, interdisciplinary consultation, and mechanisms of accountability capable of evolving alongside technological innovation. Only through this open and iterative dialogue can we hope to ensure that neurotechnologies, whether producing direct neural data or inferring mental states indirectly, are governed in a way that is not only effective and practically enforceable, but also normatively legitimate and fully respectful of fundamental rights. In this sense, the regulatory challenges raised by neurotechnologies may also be seen as an opportunity to rethink and improve broader governance practices, fostering a culture of participation and rights-respectful innovation that could benefit society as a whole.

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