THE REGULATION OF NEUROTECHNOLOGIES: CHALLENGES AND RISKS

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Abstract
Neurotechnology devices and techniques interact directly with the human brain, decoding mental processes and potentially manipulating thoughts. While they may bring wondrous benefits such as the cure for previously incurable diseases, they also allow companies and governments to potentially abuse the data they acquire and manipulate individuals and societies. Because of that, society and governments should take a proactive approach and ensure neurotechnology development follows clear safety and ethical guidelines.

Keywords
Neurotechnology, Risks, Regulation, Ethical Guidelines, Neurorights.

Summary

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1. INTRODUCTION

People with incredible powers like moving objects with their minds might sound like the plot of a Hollywood movie, but that scenario is slowly transitioning into reality as scientific developments turn once-imaginary abilities into everyday life, notably when it comes to devices and techniques capable of directly interacting with the human brain using neurotechnology. According to Rafael Yuste, technology is on the path to allow devices to "decode people's mental processes and directly manipulate the brain mechanisms underlying their intentions, emotions and decisions"[3].

Neurotechnologies constitute an important topic when discussing new technologies, having been recognized as one of the top 10 emerging technologies of 2023 by the World Economic Forum[4].

However, recent studies have shown that the increased use of neurotechnology, simultaneously presents positive prospects, societal risks, and threats to the identity of human beings[5].

While it has the potential to improve the lives of people with incurable diseases[6], it may also manipulate thoughts and decisions, which could ultimately strip human autonomy[7]. Such a scenario stirred discussions on how to regulate and ensure the safe development of neurotechnology, which gains particular significance as both governments and corporations make significant investments in these kinds of devices and techniques[8]. This article delves into the impacts of neurotechnology and how to develop an appropriate regulatory framework. To this end, it discusses what is

[3] YUSTE *et al.* 2017, 159-163.
[4] WORLD ECONOMIC FORUM 2023.
[5] YUSTE *et al.* 2022.
[6] Such as allowing patients with the sight impairment to see shapes again.
[7] YUSTE *et al.* 2022, cit.
[8] *Ibidem*.

neurotechnology and what risks it might pose to society and individuals, to finally address the challenges of regulation.

2. NEUROTECHNOLOGIES AND THEIR USE

Neurotechnology encompasses devices and techniques designed to directly interface with the brain or the nervous system, acquiring and/or imparting information, to modulate their function[9].

Expanding on this concept, a report by the OECD frames neurotechnologies as "devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons"[10].

An example of a neurotechnology would be a device capable of reading the brain's electrical impulses so the user can issue commands to a computer without the need for other forms of interaction such as a mouse or a touch screen.

Another notable use of neurotechnology involves stimulating the brain to elicit desired actions or results, such as transmitting signals to prevent or delay the onset of Parkinson's or other diseases[11].

Recent developments include the restoration of hearing and sight conditions, as well as producing promising treatments for depression, OCD, and other mental health issues[12]. A report by UNESCO underscores the widespread use of electroencephalogram (EEG)[13] for the development of brain-computer interfaces (BCI) among neurotechnological products[14],

[9] MACCAY 2022.
[10] OECD 2021.
[11] MACCAY cit.
[12] RAMIREZ-ZAMORA *et al.* 2022.
[13] Functional magnetic resonance imaging (fMRI) can be even more effective in reading the brain, but the improved portability of EEG devices makes them more proeminent.
[14] UNESCO 2023.

allowing the recording of brain activity through invasive proceedings or the use of external devices such as electrodes attached to the scalp[15].

Moreover, the application of neurotechnology far exceeds the medical realm, such as improving mental capacity for learning in educational and professional contexts[16].

Undoubtedly, the possibilities seem nothing short of wonderful, but one must also consider the risks involved. For instance, the United States Defense Advanced Research Projects Agency (DARPA), the U.S. BRAIN Initiative, and China's Brain Project intend to increase soldier performance on the battlefield, which could lead to even more destructive armies[17].

Another relevant point of concern is the use of neurotechnology in leisure activities like video games and other forms of interactive media, as well as social media, especially as BCIs are proven to influence thought patterns and behaviors.

In addition to that, as BCIs become available to the masses, large-scale safety problems arise, particularly in a society that is already discussing the ethical issues of data protection, behavioral models, and artificial intelligence, which could and most likely will be used in conjunction with neural technology.

As it can be seen, like many other emerging technologies, neurotechnology can bring about great benefits to individuals and society, but it can also bring risks, which will be discussed in the next topic.

3. NEUROTECHNOLOGY-RELATED RISKS

The OECD's Recommendation on Responsible Innovation in Neurotechnology highlights the societal, legal, and ethical issues arising

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[15] *Ibidem.*

[16] *Ibidem.*

[17] KOSAL, PUTNEY 2023, 81-103.

from the applications of neurotechnology, considering the importance of the brain's cognitive functions to important concepts like autonomy, identity, freedom of thought, and privacy[18].

In fact, the interaction of neurotechnologies with the brain influences activities connected to the very concept of what constitutes a human being[19].

It should also be noted that the algorithms used in neurotechnology might contain gender, racial, and other biases, just like their AI counterparts, which may bring its own set of economic, social, and political implications[20] [21].

Therefore, while neurotechnology presents useful prospects, it also poses societal, ethical, and individual risks that must be addressed, so a regulatory framework can be devised for such devices and techniques.

This is in itself a challenge, but it becomes far more complex as one considers the sizable investments neurotechnology development demands, which can only be met by governmental agencies and massively funded companies such as Google, Meta, Amazon, and Apple. All these organizations have their particular goals, which may or may be detrimental to the Public Interest[22].

Another challenge comes from the vast array of neurotechnologies, which provide varied risks. Considering an article would be too short to address all kinds of neurotechnology, this article will focus on the risks associated with human augmentation, surveillance, brain data access, and brain hacking.

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[18] OECD cit.

[19] As reported by UNESCO cit., "(...) the brain is the organ most closely linked to our thoughts and memories, in short, to the core of our personality (our "self"). For this reason, the data from our brain activity are much more sensitive and valuable than any other category of personal data".

[20] MACCAY cit..

[21] YUSTE *et al.* 2017, cit.

[22] MACCAY cit.

3.1. HUMAN AUGMENTATION

The 1987 sci-fi film "Robocop" depicted a man half-human, half-machine man having to deal with internal struggles of his dual nature. After 36 years, this is a real possibility, albeit not as extreme as portrayed in the film.

Neurotechnology enables the augmentation of human beings for non-therapeutic purposes, such as improved attention, efficiency, and more. That may bring desirable possibilities such as increased productivity, but that very feature may also deepen economic inequality as augmented humans enter the market and compete with non-augmented humans.

Considering the high costs of neurotechnology, this could further inequalities between social groups, excluding those unable to afford these devices from effectively pursuing certain jobs and competing in certain markets[23].

Taking into account what previously happened with other emerging technologies in the past, it doesn't seem far-fetched to consider economically privileged groups using this technological edge to dominate markets and compete on unequal terms[24].

Besides, the risks associated with the use of augmentation technology by healthy individuals are largely unknown, severely impacting cost-benefit analysis, which could skew society toward large-scale adoption before they are actually safe to use.

Another point of contention regarding augmentation devices and techniques is related to their military use, which could pose security and ethical issues as neurotechnology becomes widespread on the battlefield. In

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[23] An example of this is the EMOTIV company, that sells neurotech devices ("world's most trusted wireless EEG platform"), with prices raging from $399 to $2.099 (https://www.emotiv.com/shop/).

[24] YUSTE *et al.* 2017, cit.

fact, UNESCO expresses deep concerns regarding the heavy investments made by governments to develop warfare-related neurotechnology[25].

3.2. SURVEILLANCE, BRAIN DATA ACCESS, AND BRAIN HACKING

One notable example of surveillance through the use of neurotechnology comes from a presentation by Professor Nita Farahany at the World Economic Forum, in which she showed how brain activity could be used to surveil employees' activities, engagement, thoughts, and other data[26].
It goes to show that if neurotechnology become widespread, those who own and produce these devices will gain access to our mental states and, possibly, our thoughts[27].
While technology may not have arrived at this juncture, its accelerated development is fast approaching a point in which brain surveillance becomes a reality.
This becomes more concerning as similar issues have been observed regarding personal data and the internet, with pervasive privacy breaches, discriminatory practices, and biased algorithms, even in countries with protective legislation.
It is not hard to imagine how the brain reading capabilities of neurotechnology may increase these problems, especially in situations in which the subject has no other choice than to share their data, like in a workplace environment or under subpoena.

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[25] On that subject: "While governments and military research organizations are among the main drivers of neurotechnology innovation, the use of neurotechnology for military and security purposes is currently not sufficiently governed nor monitored to ensure compliance with international humanitarian laws and ethical norms". UNESCO cit., 43.
[26] FARAHANY 2023.
[27] MACCAY cit.

Besides, since the very notion of human interaction involves individual discretion on what and what not to reveal, these technologies have the potential to strip the subject's autonomy to decide what to share, as this information might be extracted from their brain without consent[28].

Furthermore, the ethical dilemma stemming from this unprecedented access to data is only exacerbated by the fact that those who hold such data may use it to manipulate people's behavior for their own agenda, which may not align with ethical principles or legal standards[29].

In addition to that, not only corporations and governments might have access to brain data. It is technically viable for other agents to gain unauthorized access to the brain through neural hacking, including the extraction of sensitive information or even the manipulation of individual behavior. Of course, most hacking activities have been criminalized and/or regulated for years, but neurotechnology may give them a whole new dimension[30].

Moreover, intrusions into people's brains can potentially bring even more harm than the violation of mental privacy, as they may also impact neural computation, thought processes, psychological continuity[31], and mental integrity[32].

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[28] *Ibidem.*

[29] According to UNESCO cit., 43, "these third parties could be vary varied: companies for marketing purposes, employers interested in looking into their employees' minds to monitor their concentration at work, schools wanting to scan children's brains to see if they are paying enough attention to lessons, and even authoritarian States interested in identifying opponents to the regime".

[30] MACCAY cit.

[31] According to Marcello Ienca and Roberto Andorno, psychological continuity refers to people's perception of their identity, which can be altered by neurotechnology and neural hacking.

[32] IENCA, ANDORNO, 2017.

This evidences that, while neurotechnology can and probably will bring many benefits, it also carries potential risks to individuals, society, democratic institutions, and health if left unchecked.
In light of that, scholars like Rafel Yuste and Sara Goering claim that the existing ethical guidelines and laws for technology are insufficient to ensure the safety of neurotechnology, evidencing the need for regulation[33].

4. NEURORIGHTS AND THE REGULATION OF NEUROTECHNOLOGIES

Given the risks involved with neurotechnology, scholars have been advocating the need for societies to define and recognize neurorights as human rights. In a seminal article on Nature, Rafael Yuste and the Morningside Group[34] presented what they consider the four main ethical challenges of neurotechnology: privacy and consent, agency and identity, augmentation, and bias[35].
When it comes to privacy, citizens should have the ability to keep their neural data private by being able to opt out of sharing information. The scholars even say opting out of sharing information should be the default choice in any neurotechnology device. Besides, any consent should only be given under clear information as to who will use brain data, for what purposes, and for how long[36].
Expanding on that, MacCay notes the importance of consent, given the deeply personal nature of the data neurotechnology might access, in

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[33] YUSTE *et al.* 2017, cit.
[34] A group composed of neuroscientists, neurotechnologists, clinicians, ethicists, and machine-intelligence engineers, with representatives from Google and other tech companies.
[35] YUSTE *et al.* 2017, cit.
[36] *Ibidem.*

addition to the profound interference it can have on the subject's mental experience. For this reason, the author suggests that current legislation about data privacy may not be enough to effectively regulate the situation[37].
Yuste and the Morningside Group also advocate that neurotechnology must ensure their users' agency and identity. This gains further significance as the scholars highlight that people under deep-brain stimulation often report an altered sense of identity, which could lead to deep debates on the nature of the self and personal responsibility[38].
Corroborating this perspective, Carlessi, Borges, and Calgaro alert to the informational vulnerabilities and asymmetries between individuals and corporations, which could prompt consumers to give away their autonomy, cognitive freedom, and mental privacy[39].
Yuste and the Morningside Group also argue that workplace pressures may force people to adopt augmentation technologies to enhance their endurance, sensory capacity, and/or mental capacity, which may have profound impacts on societal norms, as well as deepen inequalities[40].
The last concern they present is the biases that could be embedded in neural devices, which have been previously discussed in this article[41].
Due to these concerns, Yuste and the Morningside Group advocate that neurorights[42] should be included in international treaties and conventions, especially the 1948 Universal Declaration of Human Rights[43].
However, despite the obvious importance of protecting neurorights, regulating neurotechnology can bring its own set of challenges, since many of its issues are still conjecture or not yet clear how problematic they might be.

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[37] MACCAY cit.
[38] YUSTE *et al.* 2017, cit.
[39] CARLESSI *et al.* 2022, 372-392.
[40] YUSTE *et al.* 2017, cit.
[41] *Ibidem.*
[42] Clauses addressing these concerns on legislation and international treaties.
[43] YUSTE *et al.* 2017, cit.

Besides, it may be hard to predict how regulation may or may not hinder technological development. Because of that, more libertarian-leaning groups and individuals may resist any legislation regarding merely hypothetical issues[44].

Adding to that uncertainty, at the time of this writing the United States of America and China[45] lack any relevant legislation or regulations regarding neurotechnology. While the US does indeed have legislation governing clinical trials and other steps of medical technology development (which encompass a significant part of neurotechnology), it lacks specific guidelines for the issue at hand[46].

In contrast, the trailblazer when the comes to neurotechnology regulation is Chile, which is amending its constitution to provide neurorights for its citizens, seeking to ensure the right to brain data privacy, personal identity, and self-determination in face manipulative technologies[47].

In Brazil, constitutional amendment project no. 29/2023 intends to safeguard the protection of mental integrity and algorithmic transparency by making them constitutional rights. In it, Brazilian legislators acknowledge the significance of neurotechnologies and the positive impacts they may yield, while simultaneously harboring concerns about their ethical and societal implications [48].

Spain's initiative came through its Chater of Digital Rights, which has a chapter regarding neurotechnologies. The document provides conditions, limits, and safeguards for the implantation of neurotechnologies, for the purposes of (i) preserving individual identity as a person's sense of self, (ii)

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[44] MACCAY cit.

[45] The leading countries when it comes to neurotechnology.

[46] ERDEN, BREY 2023, 1235-1241.

[47] CHILE, *Constitución Política de La República*, 2005 (https://www.camara.cl/camara/doc/leyes_normas/constitucion.pdf.).

[48] BRASIL, *Proposta de Emenda à Constituição nº 29*, 2023. Altera a Constituição Federal para incluir, entre os direitos e garantias fundamentais, a proteção à integridade mental e à transparência algorítmica.

guaranteeing individual self-determination, sovereignty, and freedom in decision-making, (iii) safeguarding the confidentiality and security of data obtained or regarding their brain processes, and full control over them, (iv) regulating the use of human-machine interfaces which could affect physical or psychological integrity, and (v) ensuring that decisions and processes based on neurotechnologies are not conditioned by the provision of data, programs, or information that are incomplete, undesired, unknown, or biased, or by interference with neuronal connections[49].

In the same vein, France published the Charter for the Responsible Development of Neurotechnologies, which established commitments to (i) protect personal brain data, (ii) ensure reliability, safety, and security of medical and non-medical devices, (iii) develop an ethical and deontological communication, (iv) prevent misuse, malicious applications, and manipulation, and (v) take into account societal expectations[50].

It is worth mentioning that the Declaration of Internet at the Italian Chamber of Deputies (Italy) and the Data Ethics Commission (Germany) also discussed themes concerning neurotechnology.

Similar movements toward regulation have been made in the UK, as the Regulatory Horizons Council (RHC), published recommendations on the safe and rapid development of neurotechnology, which were addressed by the Secretary of State[51] [52].

In the same vein as these legislation efforts, the OECD published the Recommendation on Responsible Innovation in Neurotechnology, which

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[49] SPAIN, *Charter of Digital Rights*, 2021 (https://portal.mineco.gob.es/RecursosArticulo/mineco/ministerio/participacion_publica/audiencia/ficheros/Charter%20of%20Digital%20Rights.pdf).

[50] France, *Charte de développement responsable des neurotechnologies*, 2022 (https://www.enseignementsup-recherche.gouv.fr/fr/charte-de-developpement-responsable-des-neurotechnologies-87964).

[51] MACCAY cit.

[52] https://www.gov.uk/government/publications/regulatory-horizons-council-the-regulation-of-neurotechnology.

embodied nine principles related to the development of such technologies: (i) promoting responsible innovation, (ii) prioritizing safety assessment, (iii) promoting inclusivity, (iv) fostering scientific collaboration, (v) enabling societal deliberation, (vi) enabling capacity of oversight and advisory bodies, (vii) safeguarding personal brain data and other information, (viii) promoting cultures of stewardship and trust across the public and private sector, and (ix) anticipating and monitoring potential unintended use and/or misuse [53].

Moreover, the recommendation provides guidelines for the neurotechnology innovation process (i.e., research, investment, regulation, commercialization, and technology transfer), with the overarching goal of maximizing benefits and mitigating risks. In light of these recent movements, it is clear that governments and institutions are becoming aware of the challenges imposed by neurotechnology. However, while these are certainly steps in the right direction, it is unclear how effective they might be in addressing the risks associated with neurotechnology.

While they evoke and protect important principles, the uncertainties surrounding the development of neurotechnology devices make it unclear whether these legislations will provide design guidelines that would ensure safety.

In that sense, any effective regulation should have clear guidelines that enable scientific and economic development, but also address the main concerns regarding neurotechnology, such as Privacy and consent, agency and identity, augmentation, and bias.

Building on this viewpoint, UNESCO recommends that any neurotechnology regulation should address three main questions: consumer awareness of adverse effects, the means through which the consumer might get effective information about these technologies to make an informed decision, and consumer protection against unruly economic interests[54].

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[53] OECD cit.

[54] UNESCO cit.

These could be achieved through the following steps: fair communication/information process, availability of competent and/or medical supervision, truthful information and transparency regarding commercial interests, clear explanation of the state of scientific/technological progress and having neurotechnology be securely and ethically designed by default [55].

Adding to UNESCO's recommendations, algorithm transparency presents itself as crucial factor when it comes to emergent technologies. Scholars are already strongly advising it for devices and techniques that use machine learning and other techniques described as artificial intelligence, in order to increase their accountability[56].

It seems reasonable that the same principle be applied to neurotechnology.

Another step that could bring effective regulation would be the creation of regulatory agencies or other governing bodies. Considering the highly technical nature of neurotechnology, a team of experts could be required to deal with its issues.

Many countries are already creating similar bodies to deal with Artificial Intelligence, Data Protection, and other issues arising from emergent technologies, so it does not seem far-fetched to assume that similar solutions could be employed toward neurotechnology.

Considering the challenges arising from neurotechnology are not yet fully known, a regulatory or governing body could adapt faster to its changes than just legislation, making it a potentially more feasible solution.

In any case, society and legislators should pay close attention to these issues and have a proactive attitude toward regulation and safety protocols since the specific challenges of neurotechnology are not yet clear.

That would allow neurotechnology to incorporate basic principles to ensure security and ethical design from its inception, allowing more sustainable and

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[55] *Ibidem.*

[56] BLACKLAW 2018.

ethical development, and avoiding many issues that befell emergent technologies in the recent past.

5. CONCLUSION

The spread of neurotechnology in the consumer market is now becoming a reality. For example, Meta is developing "third generation smart glasses" with a viewfinder display and neural interface smartwatch, hoping to launch by 2025. Likewise, other neurotech companies are starting to expand their business, demonstrating the necessity of its regulation as soon as possible.
The potential benefits of these technologies are undeniable, but the risks should not be ignored, as they may impact human health, autonomy, identity, mind, and freedom, among other issues, that could cause societal, economic, and ethical problems.
Considering this scenario, society and regulators should not take a passive approach toward these technologies but take part in these discussions and promote regulation to prevent risks, as observed with similarly disruptive technologies such as AI and social networks.
To that end, this article proposes that neurotechnology development should at the very least address ethical priorities such as privacy, algorithmic transparency, identity, and non discrimination, which could be the guidelines for legislation and governing bodies regulating these devices and techniques.

REFERENCES

BLACKLAW, Cristina, *Algorithms: Transparency And Accountability*, in *Philosophical Transactions of the Royal Society A*: *Mathematical, Physical and Engineering Sciences*, August 16, 2018.

CARLESSI, Mariana M. *et al.*, *Tecnologias Persuasivas E Neurodireitos: A Tutela Dos Consumidores Nas Redes Sociais Na Sociedade Consumocentrista*, 372-392, in *Revista de Direito Brasileira*, 32, 12/2022.

ERDEN, Yasemin J., BREY, Philip, *Neurotechnology and Ethics Guidelines For Human Enhancement: The Case of the Hippocampal Cognitive Prosthesis*, 1235-1241, in *Artificial Organs*, 47, 8/2023.

FARAHANY, Nita A., *Ready for Brain Transparency?*. in *YouTube*, January 20, 2023 (https://www.youtube.com/watch?v=hfqD5aW0X5U&t=1588s).

IENCA, Marcello, ANDORNO, Roberto, *Towards new human rights in the age of neuroscience and neurotechnology*, in *Life Sci Soc Policy*, 13, 5/2017.

KOSAL, Margaret, PUTNEY, Joy, *Neurotechnology and international security: Predicting commercial and military adoption of brain-computer interfaces (BCIs) in the United States and China*, 81-103, in *Politics and the Life Sciences*, 42, 1/2022.

MACCAY, Allan, *Neurotechnology, law and the legal profession*, Horizon Report for The Law Society, London, August 2022.

OECD, *Recommendation on Responsible Innovation in Neurotechnology*, 2021 (https://www.oecd.org/science/recommendation-on- responsible-innovation-in-neurotechnology.htm).

RAMIREZ-ZAMORA, Adolfo *et al.*, *Deep Brain Stimulation Think Tank: Updates in Neurotechnology and Neuromodulation*, II, in *Frontiers Human Neuroscience*, 16/2022.

UNESCO, *The Risks and Challenges of Neurotechnologies For Human Rights*, New York, 2023 (https://unesdoc.unesco.org/ark:/48223/pf0000384185).

WORLD ECONOMIC FORUM, *Top 10 Emerging Technologies of 2023*, June 26, 2023 (https://www3.weforum.org/docs/WEF_Top_10_Emerging_Technologies_of_2023.pdf).

YUSTE, Rafael *et al.*, *Four ethical priorities for neurotechnologies and AI*, 159-163, in *Nature*, 551, 7679/2017.

YUSTE, Rafael *et al.*, *NeuroRights: A Human Rights Solution to Ethical Issues of Neurotechnologies*, in SILVA, Pablo L., VALERA, Luca (eds.), *Protecting the Mind: Challenges in Law, Neuroprotection, and Neurorights*, Berlin-New York, 2022.