A Comprehensive Analysis of Neurotechnologies in the Context of Human Rights: Consequences, Challenges, and Successes

Rehman Hassan,[1 2 3 4 5 7] Yannick Mofor,[7 *] Dana Garibaldi, [8 *] Luna Abadía, [9 12 *] Sam Hosseini-Moghaddam, [7 *] Nora Sun,[8 10 †] Rishab Ghosh, [†] Jad Abdel Nour, [3 11 †] Richard Wang, [2 ‡] Sahil Sood, [3 8 11 ‡] & Nipun Gorantla [7 ‡]

[1] Partnership for Maternal, Newborn, and Child Health, World Health Organization (WHO)

[2] Child-Friendly Cities Initiative Youth Council, United Nations Children's Fund (UNICEF)

[3] Young Champions Network, United Nations Refugee Agency (UNHCR)

[4] iCure Health International 501(c)(3)

[5] Citizen Outreach Coalition

[6] Girl Up, United Nations Foundation 501(c)(3)

[7] Stanford University

[8] Harvard University

[9] Duke University

[10] Talaria

[11] HYPE 501(c)(3)

[11] United Nations Women for Peace Association (UNWFPA)

[12] Plan International

[*] These authors contributed equally to this work

[†] These authors contributed equally to this work

[‡] These authors contributed equally to this work

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Minds Unbound: Safeguarding Human Rights through Neurotechnology Regulations in the United States

Ethical implications of neurotechnology are a pivotal consideration to effectively introduce new technological liberties, as they present a high potential to impact both personal privacy and cognitive liberty. In the United States, addressing these implications is imperative as the world's largest healthcare market, where approval and regulations may mean not only an ensured path towards success for most products but too sets the precedent for many international standards.

As the FDA is responsible for approving and regulating the devices used in neurotechnology, there is a set of guidelines where devices are regulated based on the related risk associated with their intended use. There are three main categories of risk and paired action: premarket notification for low to low-moderate-risk devices which are comparable to existing devices, premarket approval for moderately-high to high-risk devices that are not significantly comparable to existing devices, requiring clinical data from manufacturers in order to ensure safety and *de novo* classification for low to moderate risk with no comparable similar device, requiring a request sent to the FDA to conduct an independent investigation in order to ensure safety.[1]

Although the FDA addresses the physical safety of said technology, the moral and ethical aspect is less explored. Currently, the National Institutes of Health, National Science Foundation, and Department of Defense all play a role in the development and moral concerns of these potential neurotechnologies.[2] Through external research combined with institutional board reviews, many neurotechnologies are evaluated for their morality; however, many technologies developed in the private sector continue to face limited scrutiny, failing to guard many fundamental human rights. Often these systems rely on the judicial system, rather than peripheral sources and tangentially qualified government resources.

The United States of America has multiple companies in both the public and private sector developing such technology in the United States. One of the largest private companies in the private sector is Neuralink. Founded by Elon Musk, the company employs a multidisciplinary approach with a primary objective of developing inducible brain-computer interfaces (BCI). Through this, the company envisions bridging the gap between artificial intelligence and human

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[1] "Regulatory Overview for Neurological Devices - FDA." 20 May. 2021, https://www.fda.gov/medical-devices/neurological-devices/regulatory-overview-neurological-devices. Accessed 2 Jul. 2023.

[2] "Neurorights: what they are and their connection with neuroscience." https://www.iberdrola.com/innovation/neurorights. Accessed 2 Jul. 2023.

cognitive abilities, in hopes to improve and address neurological conditions.[3] This technology has the potential to drastically affect multiple facets of neuroengineering and medical treatment in the future.

Additional aims of Neuralink include being able to create an interface by which humans can merge consciousness with artificial intelligence, and envision a future through symbiotic interaction. Certain concerns surround the privacy of the data collected, as human cognition is being stored in large sortments which provide extensive insight into their natural consciousness, and a breach of such data would be an inexcusable invasion of privacy with high implications.[4] Another aspect under scrutiny is the combination of human cognition and computer operation. This places concern on external control and manipulation through the intricate control of the symbiotic system created between the interface and person. Finally, healthcare disparities may make such treatment inaccessible to a large portion of the world population who would benefit from such treatment, creating what experts describe as a "neurodivide," If these concerns are addressed, the described technology presents the potential to revolutionize healthcare on a global scale, and can provide data needed to create impactful forms of treatment.[5]

The Risks and Challenges of Neurotechnologies for Human Rights in the European Union

The European Union (EU) follows similar practices regarding regulations to the U.S., with executive control over neurotechnologies falling under the European Medicines Agency (EMA), a body with functions similar to that of the FDA in the United States. New neurotechnological equipments are held to the same vigilance as medical equipments and technologies in the EU. Importantly, however, the European Union also incorporates the landmark and globally influential General Data Protection Regulation (GDPR), which provides overall protections for individuals' data, including mental data. However, existing loopholes within the GDPR relating to neurotechnologies have been noted as being exploitable, resulting in potential human rights abuses relating to the unethical collection and usage of brain or mental data.

A 2021 study conducted by the Council of Europe, a human rights organization associated with the EU, highlighted the lack of comprehensive protections for neural data in the EU. Namely, privacy rights in the EU specifically protect civilians in cases where user data is directly used for specific purposes, by either corporate or non-corporate entities. This creates an important controversy with brain data, as existing neurotechnologies do not directly use brain data, instead culminating this mental data to make strong inferences, which are not protected by the GDPR or

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[3] "An Integrated Brain-Machine Interface Platform With Thousands of ...." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6914248/. Accessed 2 Jul. 2023.

[4] "Engineering-Ethics-of-Neuralink-Brain-Computer-Interfaces-Devices ...." 19 Feb. 2021, https://www.researchgate.net/profile/Akram-Jawad/publication/349506653_Engineering_Ethics_of_Neuralink_Brain_Computer_Interfaces_Devices/links/6034302f299bf1cc26e450f1/Engineering-Ethics-of-Neuralink-Brain-Computer-Interfaces-Devices.pdf. Accessed 2 Jul. 2023.

[5] "An Examination of Prospective Uses and Future Directions of ... - NCBI." 30 Mar. 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8083990/. Accessed 2 Jul. 2023.

EU policies. One key lacking example in the EU relates to the compelled collection of a person's neurological data during questioning by law enforcement or in a court of law. As this data can only be used inferentially, and not directly, the participant's right to privacy and silence can thus unethically be overruled, allowing for the inclusion of this data without participant consent.

An Evaluation of The Specific Human Rights that Neurotechnology Threatens

As developments in neurotechnology accelerate, the fast-paced ambition and aspirations of neuro-entrepreneurs may outpace the conscientious efforts of neuroethics advocates. Ienca and Adorno outline the threat to human rights in three categories: mental privacy, mental integrity, and psychological continuity.[6] These priorities can be applied to articles enamored in the United Nations Universal Declaration of Human Rights.[11]

Mental privacy is consistent with Article 12: "No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honor and reputation." [7]Advances in neurotechnology pose great threats to personal privacy. Current neurotechnology methods dating back to the 1960's, such as electroencephalography (EEG), record electric signals from the brain and send results to external databases.[8] As more complex biometrics are able to be collected, patients are more vulnerable to data breaches where their data can be sold to third parties and used against them. It is widely known that civilians' personal info can fall privy to the hands of large companies. For example, the infamous Facebook scandal where 87 million users' data was sold to the Cambridge Analytics consulting group for targeted advertisements.[9] If the databases that stored neural data were breached, the neural information of civilians can be used for commercial gain.

The right to mental integrity is consistent with Article 5: "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment." Neurotechnology has the potential to alter patients' personalities and sense of self. In a study conducted by Walter Glannon, a patient underwent Deep Brain Stimulation (DBS), an electrode therapy to treat Parkinson's disease. After the procedure, the patient was in a heightened state of euphoria unrecognizable to his family.[10] This case opens up frightening possibilities with complex ethical dilemmas such as: If neurotechnology can alter personalities to be happier, how do we protect against this technology being used maliciously to induce anger or sadness? Secondly, even if the mental results are positive, is it ethical to alter someone's identity without medical necessity?

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[6] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.
[7] "Universal Declaration of Human Rights - the United Nations." https://www.un.org/en/about-us/universal-declaration-of-human-rights. Accessed 2 Jul. 2023.
[8] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.
[9] "Facebook sued over Cambridge Analytica data scandal - BBC News." 28 Oct. 2020, https://www.bbc.com/news/technology-54722362. Accessed 2 Jul. 2023.
[10] "Pattern theory of self and situating moral aspects - Springer Link." 7 Nov. 2020, https://link.springer.com/article/10.1007/s11097-020-09708-9. Accessed 2 Jul. 2023.

Lastly, the right to psychological continuity is consistent with Article 3: “Everyone has the right to life, liberty and security of person.” Psychological continuity is the prioritization of individuals keeping their sense of identity, but neurotechnology has the potential to endanger this right. A study showed that after DBS, patients experienced difficulties in their relations with themselves, their spouses, their families, and their socio-professional environment.[11] It is possible that these effects may worsen as more invasive neurotechnology enters the market. The potential for these new technologies are hopeful, but scientists must proceed with immense caution and ethical consideration.

The Neuroethics Conundrum: Balancing Progress with Human Rights

Numerous human rights may be adversely impacted by the development and use of neurotechnology. First, neurotechnology threatens many citizens’ right to safety. Neurotechnologies cost millions, sometimes billions, of dollars to produce and sell,[12] and when widely implemented, will likely be more accessible to wealthier populations.[13] These technologies will then enable wealthier populations to augment their physical or intellectual capabilities, such as through super-military analysts and soldiers, allowing these wealthy countries or corporations to dominate over disadvantaged groups of people.

The implementation of neurotechnology too threatens the right to privacy. Widely-implemented neurotechnologies, such as electroencephalograms (EEGs), have already been designed to measure and monitor brain activities; advanced EEGs can approximate a patient’s internal state and emotional landscape to high degrees of accuracy.[14] Similarly, developing invasive technology, such as Brain Computer Interfaces (BCI), rely on collecting neural activity from a user to drive their functions, resulting in sensitive data on user thoughts and behavior being uploaded and stored in the BCI, oftentimes with insufficient encryption. This lack of encryption as well as the use of this technology to potentially train artificial intelligence to improve this technology constitutes a major invasion of privacy for all those who use this technology.

Beyond privacy, neurotechnologies also present a threat to the right to autonomy. Developing neurotechnologies capable of reading and monitoring a patient’s thoughts and emotions is only the first step. Developments have already begun for neurotechnologies that fundamentally edit a patient’s mental integrity; the U.S. Defense Advanced Research Projects Agency is developing

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[11] "Neurosurgery in Parkinson disease: a distressed mind in a repaired ...." https://pubmed.ncbi.nlm.nih.gov/16801642/. Accessed 2 Jul. 2023.
[12] "Concerns in the Blurred Divisions between Medical and Consumer ...." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8813044/. Accessed 2 Jul. 2023.
[13] "Four ethical priorities for neurotechnologies and AI - Nature." 9 Nov. 2017, https://www.nature.com/articles/551159a. Accessed 2 Jul. 2023.
[14] "Emotion detection using electroencephalography signals and a zero ...." 29 Mar. 2021, https://www.nature.com/articles/s41598-021-86345-5. Accessed 2 Jul. 2023.

an integrated circuit chip that sends precise signals for a patient to complete a specific action.[15] Such threats to fundamental human rights call for strict regulatory legislation and reinforcement to ensure that no group of individuals, especially physically vulnerable populations, are being taken advantage of.

A Tangled Web: Uncovering the Perils of Neurotechnology Testing and its Ramifications on Human Rights

The testing process for new neurotechnologies is highly undefined and poses numerous risks for the human rights of the patients involved. Mature neurotechnology already intends to record and modify human behavior and thought; faulty neurotechnology that is in testing has unlimited potential to cause physical and psychological damage.[16] For example, studies have noted that a neurotechnology which detects anxiety when the patient is feeling none may actually lead the patient to experience anxiety because of this result.[17] For example, Neuralink, which has not yet progressed to human testing, has killed an increasing number of animal subjects because failed tests needed to be repeated.[18] Complex technology, such BCI, will naturally result in failed trials late into clinical testing, which may result in an enormous number of lives damaged or sacrificed for a neurotechnology that never succeeds.

Risks associated with neurotechnology testing will only be amplified in the development of consumer-oriented neurotechnologies. Because neurotechnologies are novel and poorly understood by the public, insufficient guidelines are in place to regulate their production and distribution, inevitably leading to inaccurate information, accidents, and unforeseen side effects.. Direct-to-consumer neurotechnologies developed in corporate settings for mass production and sale will result in neurotechnologies being provided to consumers that may not be correct or effective and may be used incorrectly by consumers.

Vulnerable Groups to Neurotechnology Proliferation

Any technology designed without the awareness, insight, and consultation of specific groups will ultimately lead to biases that put marginalized groups at risk. Neurotechnologies pose significant risks if not developed with this conscience in mind. Particularly vulnerable groups include criminal offenders, neurodivergent people, women, and people of color.

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[15] "Four ethical priorities for neurotechnologies and AI - Nature." 9 Nov. 2017, https://www.nature.com/articles/551159a. Accessed 2 Jul. 2023.
[16] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.
[17] "Oversight of direct-to-consumer neurotechnologies - Science." https://www.science.org/doi/10.1126/science.aav0223. Accessed 2 Jul. 2023.
[18] "Exclusive: Musk's Neuralink faces federal probe, employee backlash ...." 6 Dec. 2022, https://www.reuters.com/technology/musks-neuralink-faces-federal-probe-employee-backlash-over-animal-tests-2022-12-05/. Accessed 2 Jul. 2023.

By fitting complex statistical models to functional magnetic resonance imaging (fMRI) brain scan results, neuroscientists claim that they may soon decode individuals' feelings, thoughts, decisions, intentions, and behaviors from testing.[19] This technology can have devastating ramifications that lead to coerced self incrimination during criminal investigations, a practice widely banned in the democratic world.[20] A reality where criminal justice systems can monitor the thoughts of individuals under investigation leads to an ethical, almost dystopian question of the permissibility of invasive mental decoding.

Worldwide, neurodivergent people comprise almost 13 percent of the population, according to research by UNESCO. These "[trigger] care-related costs that account for up to a third of total health expenses in developed countries," and in less economically developed countries as well, the agency notes.[21] Because of this, neurodivergent communities may be more inclined to use new neurotechnologies to explore potential positive impacts for physical and mental health. Yet as neurodiversity continues to be undervalued in the technology sector, development processes can gather neurotypical biases. It is important to note that neurodivergent communities often push back against the notion that neurodivergence is a condition that needs fixing. For example, PAppropriate and conscientious design as well as marketing is needed, and this will only be accomplished with neurodivergent people centered in the workplace.

Women and non-binary people are at risk for receiving gender-based violence due to the invading use of neurotechnologies, such as by a family member or intimate partner. Given that neurotechnology is increasingly able to track emotions, chart memories, or read levels of fatigue,[22] abusive situations could result from women being forced to use devices as surveillance methods. The global gender-digital divide extends to the neural divide—particularly when it comes to accessing expensive technologies regulated for clinical use without just financial wellbeing and agency.

The gender-based gap was established as a critical issue for U.N. Member States during the 2023 March Commission on the Status of Women. Member states recognized "that adolescent girls…can disproportionately face discrimination, violence that occurs through or is amplified by the use of technology…which prevents them from accessing the full benefits of digital technologies and meaningful participation in society."[23] The 1995 Beijing Declaration and

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[19] "Limits of decoding mental states with fMRI - PubMed." https://pubmed.ncbi.nlm.nih.gov/35219121/. Accessed 2 Jul. 2023.
[20] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.
[21] "UNESCO to lead global dialogue on the ethics of neurotechnology" 6 June 2023, https://www.unesco.org/en/articles/unesco-lead-global-dialogue-ethics-neurotechnology. Accessed 2 Jul. 2023.
[22] "Neurotech at Work" March-April 2023, https://hbr.org/2023/03/neurotech-at-work. Accessed 2 Jul. 2023.
[23] "CSW67 Agreed Conclusions" 20 March 2023, https://documents-dds-ny.un.org/doc/UNDOC/LTD/N23/081/71/PDF/N2308171.pdf?OpenElement. Accessed 2 Jul. 2023.

Platform for Action also declared "that it is essential that all women not only benefit from technology, but also participate in the process from the design to the application, monitoring and evaluation stages," in the implementation of technology as well as legislation.[24]

Communities of color face a tumultuous history of unjust and non-consensual medical experimentation that has fostered trauma and understandable skepticism of technologies with medical implications. Ensuring people of color are not left behind requires equal access to information and education and dismantling practician biases. Women and communities of color in "developing countries, including the least developed countries and small island developing States and African countries" must also be centered.[25] Most importantly, a proper assessment of multiple and intersecting forms of discrimination for specific technologies in early development states must be enforced. Under-represented groups may be left out of the benefits of neurotechnology advancements if the datasets to train these technologies come from homogenous populations. Artificial intelligence, a technology that is developing alongside neurotechnology, has shown signs of being racist and sexist due to bias in the data they are trained on.[26] Strict regulation is needed to ensure that no voices are left behind in the conversation on neuroethics and access.

Safeguarding Neurorights: Addressing Risks and Ensuring People-Centered Design in Neurotechnology

While neurotechnologies may be able to help with common ailments such as strokes or chronic pain, their design must be people-centered, ensuring the general public receives sufficient information, particularly detailing the sourcing of data. Risks will only be amplified in the arena of consumer-oriented neurotechnologies. Because neurotechnologies are novel and poorly understood by the public, insufficient guidelines may inevitably lead to inaccurate information, accidents, and unforeseen side effects.

Risks must continue to be charted in areas that are currently unforeseen, such as potential effects to future generations of those who use neurotechnologies today—and the ethics confronting the inability of future generations to choose whether or not to be affected. The testing process for new neurotechnologies is also highly undefined and poses numerous risks for the human rights of the patients involved. Mature neurotechnology already intends to record and modify human behavior and thought; faulty neurotechnology that is in testing has unlimited potential to cause

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[24] "CSW67 Agreed Conclusions" 20 March 2023, https://documents-dds-ny.un.org/doc/UNDOC/LTD/N23/081/71/PDF/N2308171.pdf?OpenElement. Accessed 2 Jul. 2023.

[25] "CSW67 Agreed Conclusions" 20 March 2023, https://documents-dds-ny.un.org/doc/UNDOC/LTD/N23/081/71/PDF/N2308171.pdf?OpenElement. Accessed 2 Jul. 2023.

[26] "These robots were trained on AI. They became racist and sexist.." 16 Jul. 2022, https://www.washingtonpost.com/technology/2022/07/16/racist-robots-ai/. Accessed 2 Jul. 2023.

physical and psychological damage.[27] For example, studies have noted that a neurotechnology which detects anxiety when the patient is feeling none may actually lead the patient to experience anxiety because of this result.[28]

One method that can be utilized is an international human rights gathering of governmental bodies joined by experts in relevant fields, including scientists, philosophers, and ethicists.[29] Through this method, there can be a global and multifaceted discussion on the potential where potential harms of neurotechnologies can be identified. Following these discussions, a human rights framework that protects vulnerable populations from abuses of the technologies can be formed. While this framework would generally focus on all consumers, it could also emphasize the need for neurotechnology businesses to provide full transparency of the purpose, capabilities, and data collection of their devices to each consumer in clear language. This would ensure that all individuals — including vulnerable populations like those with disabilities, mental health issues, or poorer education — can fully understand how their rights may be impacted. The framework can then be used to create changes in legislation, helping protect human rights in each participating country.

Another method that can be used is to introduce a certification system for each neuro-technological device available on the market.[30] This may include multiple scientific studies showing clear evidence of the benefits of their device. It may also include fully transparent explanations of the device's purpose and inner mechanisms. Each device can be screened by governmental bodies and continuously monitored to ensure compliance with existing privacy and human rights laws. If any certified device were to cause adverse effects in a patient, physicians could use a reporting system to identify a governmental health-focused organization and then address the patients' health issue as needed. For example, if the brain stimulation of a neurotechnology device causes behavioral or personality changes, as has been noted in previous studies, they can be referred to psychiatric treatment to protect them from further harm.[31] This can especially benefit those with disabilities or mental health issues, whose health complications may be exacerbated by these technologies.

One particular category of neurotechnology — namely consumer-oriented neurotechnology — can amplify the risks to the neurorights of vulnerable individuals. While these technologies are more readily available to the public, as they are sold directly to consumers without physicians

[27] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.
[28] "Oversight of direct-to-consumer neurotechnologies - Science." https://www.science.org/doi/10.1126/science.aav0223. Accessed 2 Jul. 2023.
[29] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.
[30] "The risks and challenges of neurotechnologies for human rights." https://unesdoc.unesco.org/ark:/48223/pf0000384185. Accessed 2 Jul. 2023.
[31] "Towards new human rights in the age of neuroscience and ...." 26 Apr. 2017, https://lsspjournal.biomedcentral.com/articles/10.1186/s40504-017-0050-1. Accessed 2 Jul. 2023.

acting as intermediaries, they carry many considerable limitations. Many consumer-oriented neurotechnology devices have little to no original research on the effectiveness of the product, and are often only loosely based on broader scientific research. Additionally, studies have found that the public may not be well informed on what technologies can actually benefit cognition, as ¼ of adults 40 and older believe that mobile apps with brain games are the best at improving brain health, despite little evidence to support this.[32] Thus, if a technology were to advertise themselves as being able to determine one's emotional state, as is the case with many consumer EEG devices, individuals may believe the results regardless if they are actually true. This can cause psychological damage to those with mental health issues, as if the device shows a reading of "stress" or "depressed", it could make the individual more distressed about their mental state, even though they did not receive an official diagnosis. This could also affect elderly people, who may act on their fear of cognitive decline. Finally, the extent to which these devices are currently regulated is minimal, as many are advertised as "wellness technologies" and not official medical devices. This creates a potential for privacy issues or a breach of neurorights.[33]

Although neurotechnologies can violate many human rights without regulation, they too can positively impact a variety of fields in our world. They can open doors to students, teachers, and employers for improved learning within the classroom or workplace. Physical performance, such as coordination and well-being, as well as learning capabilities, can be enhanced by neurotechnologies. Specifically regarding the lives of individuals with disabilities, neurotechnologies can enable new methods of communication, movement, and interaction with the world. Individuals with amyotrophic lateral sclerosis who cannot speak can communicate using computer interfaces to translate neural signals into speech or text. Neurotechnologies allow these individuals to express their thoughts and feelings, enabling and empowering them to regain their voice.[34]

Neurotechnologies can benefit individuals with neurodegenerative diseases like Alzheimer's or Parkinson's. With the potential to detect diseases early, diagnose them, and provide personalized plans to treat and combat these diseases, neurotechnologies empower these individuals to manage these conditions and have a higher quality of life. Neurotechnologies can contribute to equal opportunities for all individuals to fully engage in society, regardless of neurological diseases.

In a June 2023 report, the UK Information Commissioner's Office (ICO) stated that "newly emerging neurotechnologies risk discriminating against people if those groups are not put at the

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[32] "Oversight of direct-to-consumer neurotechnologies - Science." https://www.science.org/doi/10.1126/science.aav0223. Accessed 2 Jul. 2023.
[33] "Neurotechnologies: The Next Technology Frontier | IEEE Brain." https://brain.ieee.org/topics/neurotechnologies-the-next-technology-frontier/. Accessed 2 Jul. 2023.
[34] "Neurotechnology: what it is, applications - Iberdrola." https://www.iberdrola.com/innovation/neurotechnology. Accessed 2 Jul. 2023.

heart of their development."[35] The ultimate goal of legislation on neurotechnology should be to secure an environment where anyone—especially marginalized groups—are able to make informed and intentional choices about their engagement with neurotechnology, and that these choices are not forced due to inequalities nor gaps in legal accountability nor insufficient regulatory oversight on the national and international levels.

While the growing field of neurotechnology can provide some benefits for patients, there are some notable risks that should be addressed. By adopting methods to identify and assess the risks and impact of these technologies on human rights, especially for vulnerable populations, the privacy, autonomy, and mental integrity of individuals can be maintained.

From Healthcare to Warfare and Reverse: How Should We Regulate Dual-Use Neurotechnology?

The current national legal framework in the United States is not adequately posed to face the challenges that the development, test and use of neurotechnologies pose to human rights. To improve the legislative landscape, the U.S. must ensure that the pathways from private development to public use are handled appropriately by regulatory bodies. The U.S. must also clarify legal language to ensure that scopes of work are defined when it comes to applying existing legal frameworks to new advances in neurotechnologies. Many existing frameworks exist that do not yet make sufficient links to neurotechnology, nor clarify whether data produced from these technologies may fall under the realms of privacy data collection.

In clinical settings, the use of neurotechnologies is highly regulated by the FDA. In fact to date, no BCI company has yet received FDA approval.[36] [37] Yet the legislative landscape continues to change. Among existing and lasting initiatives to introduce discussion regarding neuroethics, a landmark action by the United States government, the National Academies of Sciences, Engineering, and Medicine, and the Arizona State University, involved a 2016 workshop incorporating stakeholders relating to the proper methods of pursuing nanotechnological research in the future. The collaborators of this initiative highlighted the need for regulatory and advisory bodies such as the U.S. BRAIN Initiative Multi-Council Working Group to influence policy and legislative decisions. Initiated during the Obama Administration in 2013, the White House Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative continues to

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[35] "ICO warns of "real danger" of discrimination in new technologies that monitor the brain" 8 June 2023, https://ico.org.uk/about-the-ico/media-centre/news-and-blogs/2023/06/ico-warns-of-real-danger-of-discrimination-in-new-technologies-that-monitor-the-brain/. Accessed 2 Jul. 2023.

[36] "Neuralink competitor Precision Neuroscience conducts its first clinical study to map human brain signals" 23 June 2023, https://www.cnbc.com/2023/06/23/precision-a-neuralink-competitor-conducts-its-first-clinical-study.html. Accessed 2 Jul. 2023.

[37] "Who, If Not the FDA, Should Regulate Implantable Brain-Computer ...." https://journalofethics.ama-assn.org/article/who-if-not-fda-should-regulate-implantable-brain-computer-interface-devices/2021-09. Accessed 2 Jul. 2023.

function under the Biden Administration with monthly news updates on ongoing research through public and private sector partnerships.

The Interagency Working Group on Neuroscience (IWGN) is another body working to understand the U.S. Federal government's role in research and legislation. The working group is spearheaded by the U.S. White House Office of Science and Technology Policy, and includes the National Science Foundation, Department of Health and Human Services and other relevant bodies. A stronger legislative approach would ensure this process also investigates areas of ethics and human rights in collaboration with U.N. bodies.

The National Institute of Health has previously led a research group, termed the "ACD Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Working Group."[38] Although now inactive, re-activating this is a potential next step for the U.S. to take to deepen the body of research to inform legislation.

Also of particular note is the U.S. Defense Advanced Research Projects Agency (DARPA), which has spearheaded its own neurotechnology research, working under their own independent ethical advisory board. Despite the work of these bodies, it has been noted that there is a severe lack in policy regarding the proper ethical practices relating to neurotechnological research, with most research organizations relying upon independent review boards for their research, which could have critical social implications.

Further investigations of DARPA's neurotechnology practices have aimed to understand the potential judgement of "dual-use neurotechnology" research (neurotechnology holding both civilian/social and military implications) as being dual use research of concern (DURC), a label created by the United States government signifying research that could potentially be used as a harm to public civilian life as well as national security. Existing reviews have concluded that despite the potential for their role in minimizing threats to national security, dual-use neurotechnologies pose ethical and security risks, resulting in the inclusion of several areas of neurotechnology into the DURC label. Again, the need for centralized frameworks relating to the proper legal practices of neurotechnology research in the United States is almost universally highlighted.

In existing expert advisory groups and organizations in the United States, consensus remains that an "anticipatory governance" approach, one forecasting future technological developments so as to better prepare legislative protections in the wake of new frontiers in neurotechnology is needed. This similar strategy has been employed in recent history in other fields of technologies.

Scholars have noted that managing legal issues related to neurotechnologies will be difficult without careful guidelines. For example, if someone were to commit neural identity theft, where

[38] "Working Group Activities," https://acd.od.nih.gov/working-groups.html. Accessed 2 Jul. 2023.

brain data such as a person's memories are tampered with, tracking down who is responsible while the device used is not regulated inhibits the ability for legal oversight (MacKellar). Neurotechnology also presents the question of how to define criminal intent in a society in which more individuals rely upon or choose to utilize neurotechnologies to some extent (MacKellar). It remains unclear what an autonomous sense of self may be when neurotechnologies are, for instance, assisting someone with quadriplegia to move.

When technologies become so deeply essential to our lives and personal health, they begin to function like public utilities—indispensable and therefore able to set high costs that users are forced to comply with. It is worrisome that a lack of legislation can lead consumers stranded. Cases have arisen where individuals who purchased neurotechnologies were forced to maintain their devices after the company or manufacturer in charge of the installed device went out of business or ceased to provide support for customers. Legislation should clarify whether it is health providers or companies that hold responsibility to the maintenance of devices in use for clinical health purposes.

Ethical neurotechnology development would be improved through an EPA-type model which gives regulatory bodies the ability to selectively shut down companies if they demonstrate an incapacity to follow standards—in this case, for human rights, human health, and privacy.

Moving forward, legislation must work to ensure a careful system of collaboration between health officials, neurotechnology manufacturers, regulatory bodies, and a meaningfully engaged public body. Public bodies can be meaningfully engaged through targeted stakeholder engagement in regulatory review processes, both ex-ante and ex-post. Regulatory review as opposed to self-regulation is necessary. Resource gaps in funding and staffing must also be analyzed to ensure legislative bodies can attend to the speed of innovative development in this area.

Mind over matter: Examining the implications of machine brain interfaces on privacy and data protection under the GDPR.

Neurotechnologies generally depend upon recording data from a human brain or neural network, and processed this data using external devices to become applicable for both research and bodily modification purposes. Determining the domains of allowed supervision or ownership of these data extraction processes is critical to the future impact of these technologies. Privacy legislation will likely differ in clinical and non-clinical settings, for medical or human enhancement purposes, as well as depending on whether the party using these technologies is an individual, a company, or other body.

In the European Union (EU), existing legislation protecting the data of civilians both online and in-person exists mainly in the form of the General Data Protection Regulation (GDPR).

However, as a novel field of data collection, further investigation is merited into understanding whether the GDPR is capable of protecting users' mental and brain data. Importantly, it is consistently noted by the existing research that as the future implications of mental data cannot yet be known, anticipatory approaches must be taken to the protection of mental data within the current sphere of technology, with a cognizant understanding of the need for regular updates to this legislation. The major field of brain data wherein current discussions are held regards the intersections between artificial intelligence and brain-computer interfaces (BCIs), which use cognitive and emotional data gathered from the brain.

Importantly, the GDPR contains protections against the usage of individual user data, when this data can be identified on an individual level - in other words, if the data contains identifiers that relate to the specific person from whom the data is collected. Mental data itself exists in a state of limbo regarding its potential classification as a "special category" of personal data. In order to spearhead productive legislation, it must be determined whether the data produced from neurotechnologies, such as BCI-driven applications, can be classified as personal data. These are forms of data relating to race, ethnicity, sexual orientation, sociopolitical beliefs, and genetic/biometric data. States must also work to define "mental integrity" in legal terms.[39] First steps were taken in a December 2020 Chilean bill on neurorights, but elsewhere legal action is unmatched.[40]

The inferential nature of many current neurotechnologies involving the usage of mental or brain data allows for many corporations' conclusion that, as mental data is not used to directly determine any factors of a special category, it itself can therefore not be classified as a special category either. As a result, the specific usages of brain data are what allow for their potential classification under the GDPR. This creates a loophole in the GDPR, removing protections for important usages of brain data. The potential high-risk or special classification regarding the use of mental data highlights the need for the inclusion of comprehensive protections for mental data in the GDPR, despite the satisfactory protections it currently provides. Prior investigations have recommended more rigid consent structures relating to the collection of brain data, as well as stronger guidelines on the research into and usage of mental and brain data.

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[39] "What Should We Do With People Who Cannot or Do Not Want to Be Protected From Neurotechnological Threats?" 4 August 2021, https://www.frontiersin.org/articles/10.3389/fnhum.2021.703092/full. Accessed 2 Jul. 2023.

[40] "What Should We Do With People Who Cannot or Do Not Want to Be Protected From Neurotechnological Threats?" 4 August 2021, https://www.frontiersin.org/articles/10.3389/fnhum.2021.703092/full. Accessed 2 Jul. 2023.

Addressing the Regulatory Void: Neurotechnology and Human Rights in the Global Context, Proposing Normative Measures

Advancements in neurotechnology, artificial intelligence, and medicine have propelled us into uncharted territory, revolutionizing our understanding of the human brain. From brain-computer interfaces and neuroimaging techniques to cognitive enhancement technologies, neuroscientific breakthroughs have offered unprecedented opportunities to improve human health, augment cognitive abilities, and transform the way we interact with the world. However, amidst this rapid progress, a critical concern looms large – the lack of robust regulatory frameworks and normative measures to guide the ethical and responsible use of neurotechnologies.[41] [42] Proposing a range of normative and regulatory measures, this section aims to outline a framework of basic necessities that govern the responsible and ethical use of neurotechnologies on a global scale. It is important to note, however, that without effective implementation at domestic and institutional levels, global recommendations alone will be insufficient in addressing the regulatory void and ensuring the protection of human rights in the realm of neurotechnology.

One crucial normative measure is the establishment of clear, understandable standards for obtaining informed consent. Given the intimate nature of neurotechnological interventions, where access to an individual's neural activity and cognitive processes is involved, informed consent by every participant becomes paramount. This not only includes during the testing process where clinical participants will likely be used to ensure efficacy but too during processes to refine these methods through the continuous training of algorithms.[43] This will help ensure that individuals have the necessary information to make autonomous decisions about their participation and that their rights, dignity, and privacy are respected.[44] There are many critical factors that go into ensuring that informed consent is complete and effective in guarding human rights.

> Primarily, information on the purpose, potential risks and benefits, procedures, and alternatives involved in neurotechnology research or interventions must be clear and understandable to those involved.[45]

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[41] "Neurotechnology and the Law | August 2022." https://m-cacm.acm.org/magazines/2022/8/262912-neurotechnology-and-the-law/fulltext. Accessed 2 Jul. 2023.
[42] "Assessing current mechanisms for the regulation of direct-to ...." https://www.sciencedirect.com/science/article/abs/pii/S2589295920300199. Accessed 2 Jul. 2023.
[43] "Neuroscience of decision making and informed consent - NCBI." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2563331/. Accessed 2 Jul. 2023.
[44] "Artificial Intelligence and Consent: Navigating The Ethics of ...." https://www.computer.org/publications/tech-news/research/ai-and-the-ethics-of-automating-consent/. Accessed 2 Jul. 2023.
[45] "Comprehension and Informed Consent: Assessing the Effect ... - NCBI." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819424/. Accessed 2 Jul. 2023.

Moreover, this process should be transparent and collaborative, allowing individuals to ask questions, seek clarification, and have sufficient time to make informed decisions without any undue influence.

Participation must too be completely voluntary; often, clinical trials and other forms of testing take advantage of individuals in financial hardship or are hopeless, and participation must be completely voluntary and objective, considering the diverse population groups that may interact with neurotechnologies, including individuals with varying levels of neurodiversity, cultural backgrounds, and linguistic capabilities.

Special attention should be given to ensuring that informed consent processes are accessible, culturally sensitive, and tailored to the unique needs of different individuals and communities.

Also critical is ensuring that each participant has the capacity to consent, meaning that they are of age, have legal responsibility over themselves, and have been assessed to understand and appreciate the information provided, weighing the potential risks and benefits of neurotechnologies.[46]

The rights of children in regard to neurotechnologies continue to be a difficult regulatory landscape to ensure that children are able to understand what is going on, weighing the rights of the child, the rights of parents or guardians, and health.[47]

By setting clear standards for obtaining informed consent, we can empower individuals to exercise their autonomy, respect their right to make decisions regarding their own bodies and minds and protect their privacy. These standards should be integrated into research protocols, clinical practices, and the development of neurotechnology policies, fostering a culture of ethical and responsible engagement with neurotechnological advancements.

Given that these technologies deal with information as person as individuals' personal thoughts and health information such as brain activity raises significant ethical and privacy concerns. To ensure the responsible and ethical use of neurodata, robust privacy measures must be implemented, alongside legal frameworks that address issues of data ownership, control, and access rights.

The establishment of stringent security protocols to prevent unauthorized access or disclosure of neurodata to individuals other than the participant and those that the

[46] "Is written informed consent 'cast in iron' even during a pandemic?." 29 Oct. 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7598424/. Accessed 2 Jul. 2023.
[47] "Choice and Trade-offs: Parent Decision-making for ... - NCBI." 2 Jun. 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8458226/. Accessed 2 Jul. 2023.

participant indicates as eligible to view this data. It is imperative that these indications are not vague and instead reflect the totality of individuals accessing this data.

Also to ensure security, this entails implementing strong encryption measures, adopting secure storage systems, and employing strict access controls to ensure that only authorized individuals can access the data.[48]

Also, when possible data anonymization and de-identification techniques should be utilized to further safeguard individuals' privacy while still enabling valuable research and analysis.

The right to be forgotten must be available to all who utilize neurotechnologies to ensure the maintenance of full autonomy by each participant. As individuals grow and evolve, they may wish to remove or delete their neurodata from databases or research repositories, reclaiming their right to privacy and autonomy. This right recognizes that individuals should have agency over their own neurodata, empowering them to exercise control over its use and dissemination.[49]

The issue of data ownership and control is critical in the context of neurodata, given its intimate connection to an individual's thoughts and brain activity.[50] Clear legal frameworks are required to address questions of who owns the neurodata, who has control over its use, and what access rights are granted to various entities, especially in the context of intellectual property. Determining data ownership should required a careful examination of ethical, legal, and societal considerations.[51] While individuals should have primary ownership and control over their own neurodata, collaborative models that enable research institutions, healthcare providers, or other stakeholders to access and use neurodata under specified conditions may be necessary to facilitate scientific advancements and societal benefits.

Ensuring equitable access to neurotechnologies is essential to prevent the furtherance of the digital divide, addressing the potential disparities among individuals and communities from diverse backgrounds. Given that neurotechnologies hold promise in improving healthcare outcomes, enhancing quality of life, and advancing scientific knowledge, it is critical that there

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[48] "Addressing privacy risk in neuroscience data: from data protection to ...." 4 Sep. 2022, https://academic.oup.com/jlb/article/9/2/lsac025/6691730. Accessed 2 Jul. 2023.
[49] "Artificial Intelligence and the Right to Be Forgotten." https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=1816&context=faculty_scholarship. Accessed 2 Jul. 2023.
[50] "Privacy Challenges to the Democratization of Brain Data - PMC - NCBI." 5 May. 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7235278/. Accessed 2 Jul. 2023.
[51] "The Story of Artificial Intelligence in Patents - WIPO." https://www.wipo.int/tech_trends/en/artificial_intelligence/story.html. Accessed 2 Jul. 2023.

are proactive policies in place to prevent the exacerbation of existing inequalities. These policies should consider the following key factors:

> Neurotechnologies can be costly, particularly during the early stages of development and implementation. As such, these technologies might be unduly expensive, alienating individuals who may require these technologies. As such policies should focus on reducing financial barriers to access, such as through public funding initiatives, insurance coverage, or subsidies. This will ensure that individuals from diverse socioeconomic backgrounds have the opportunity to benefit from these technologies without incurring significant financial burdens.[52]
>
> Public education and awareness: promoting education and awareness programs is crucial to bridge the knowledge gap surrounding neurotechnologies. Educational disparities that exist today that are critically linked to race, ethnicity, socioeconomic status, and more should not limit access to these potentially crucial technologies. As such policies that encourage public awareness as well as the disseminate accurate information can enhance digital and technological literacy, empowering individuals and communities to understand neurotechnologies more effectively.
>
> Healthcare Infrastructure: policies should too address the need for adequate healthcare infrastructure to support the implementation and delivery of neurotechnologies. This includes the expansion of healthcare facilities to underserved areas as well as the spread of medical and scientific expertise to provide access to neurotechnological interventions and related services.

Such policies will promote inclusivity, empower marginalized communities, and harness the full potential of neurotechnologies to improve health outcomes and enhance well-being on a global scale.

International collaboration and knowledge sharing is pivotal in advancing research, establishing effective regulation, and promoting best practices. Neurotechnology research and its applications transcend national boundaries, and requiring the collective expertise and experiences of researchers, policymakers, and practitioners from around the world.[53] Thus, it is crucial to utlize international collaborational methods to fostering innovation and maximizing the potential benefits of these technologies. Policies that encourage international collaboration in neurotechnology research will both promote equity through the diversification of lived

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[52] "Abandoned: the human cost of neurotechnology failure - Nature." 6 Dec. 2022, https://www.nature.com/immersive/d41586-022-03810-5/index.html. Accessed 2 Jul. 2023.
[53] "Research collaborations bring big rewards: the world needs more." 16 Jun. 2021, https://www.nature.com/articles/d41586-021-01581-z. Accessed 2 Jul. 2023.

experiences from researchers from international backgrounds and enables the pooling of expertise, to limit overlap in similar areas.[54]

One domestic regulatory gap is the need for specific legislation that is clear in addressing the unique challenges neurotechnologies pose to the world. Neurotechnologies can collect, store, and use brain data, which can invade the privacy of individuals using these technologies. Detailed regulations must protect this privacy as information within our brains is deeply personal and sensitive. Explicit legislation that provides guidelines on consent and data security for individuals, as accessing and owning this data must be governed to control the privacy and security of individuals using neurotechnologies.[55]

The legal measures necessary to avoid human rights violations brought on by neurotechnologies are clear legislation addressing the potential disparities and ethical safeguards put in place. Neurotechnologies should be deployed and used per moral and ethical standards to ensure they aren't abused or exploited. Policymakers and governments should collaborate with bioethicists and neuroscientists to develop legislation and work together to protect human rights.[56]

The movement and sharing of neuroscience data pose a persistent challenge for international governance coordination. This gap in international data governance (IDG) stems from distinct data regulation laws between countries. As a result, data sharing across borders often comes with many risks. For neuroscientists, fear of liability can severely hinder data sharing across international institutions, limiting neuro-technological innovation and discovery.[57] Without unified and integrated policies in IDG, the right to safe and transparent data sharing across borders may be compromised.

But neuro-data must also be responsibly shared to protect the right to privacy of personal data. As neurotechnology is rapidly growing in a worldwide market, regulations on these technologies have not kept up to ensure ethical innovation, especially since much is still unknown in this field.[58] Mental privacy is at risk without transparent neurotechnology use. Stronger international regulations on the applications of neurotechnology and the collection and sharing of data will provide a step towards mental integrity and ensuring fundamental human rights.

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[54] "Benefits, Motivations, and Challenges of International Collaborative ...." 15 Feb. 2021, https://academic.oup.com/spp/article/48/2/235/6135106. Accessed 2 Jul. 2023.
[55] "Neurotechnology: Current Developments and Ethical Issues - Frontiers." 27 Nov. 2017, https://www.frontiersin.org/articles/10.3389/fnsys.2017.00093/full. Accessed 2 Jul. 2023.
[56] "Ethics of neurotechnology - UNESCO.org." https://www.unesco.org/en/ethics-neurotech. Accessed 2 Jul. 2023.
[57] "International data governance for neuroscience - ScienceDirect.com." 16 Feb. 2022, https://www.sciencedirect.com/science/article/pii/S0896627321009557. Accessed 2 Jul. 2023.
[58] "How Testing Neurotechnology On Humans Is Testing Human Rights." 21 Feb. 2022, https://www.humanrightspulse.com/mastercontentblog/okibiphj7o2e1bpn8tk74a2dy5bg68. Accessed 2 Jul. 2023.

However, a significant structural barrier stands in the way of strong regulation: ambiguity. In many countries, including the United States, the lack of an available "middle ground" with medical device regulation results in misguided, ineffective use of these devices, as evidenced by a recent legal battle regarding electric shock wearables.[59] This phenomenon is corroborated by a recent UN report which warns of the dangers with the sparse, vague regulations that currently exist for neurotechnologies, urging new regulation as a result of the lack of ethical oversight in the private sector.[60] With neurotechnology inevitably embedded within our society's future, experts believe effective regulation to be a necessary progression to preserve human rights.[61]

In the status quo, the lack of standardized regulation to establish a standard for neurotechnology is lacking, which creates ambiguity with regard to the ethical implications of neurotechnology. As such, a primary objective should be to collaborate with key countries and stakeholders internationally to create such a standard within this domain. The OECD Recommendation on Responsible Innovation in Neurotechnology is a promising initial effort, but further expansion upon this foundation is necessary to ensure clarity and uniformity amongst regulation.[62] Ultimately, this would prevent any cases from "slipping through the cracks."

Moreover, the current lack of attention to inter alia and protection of individual cognitive privacy concerns poses a risk to a cohesive societal usage of neurotechnology. Neurotechnologies such as current ones laid out used to "read" and "write" the brains of Parkinson's and Alzheimer's patients through the 24-7 closed-loop DBS pose grave ethical threats to the possession and usage of personal cognitive information.[63] As such, it is critical to outline a set of internationally recognized principles related to protecting cognition against the invasive nature of neurotechnology. Such normative measures can be modeled after Article 3 of the EU Charter of Fundamental Rights, which establishes a a bimodal relationship in the state and person to protect both physical and mental integrity.[64] By modeling after Article 3, we can explore three prudential precedents for further neurotechnology explorations: 1) free and informed consent, 2) prohibition of accessing neurological data for financial gain, and 3) the prohibition of handling / storing data in a potentially breaching manner.

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[59] "Ambiguities in Neurotech Regulation." https://issues.org/ambiguities-in-neurotechnology-regulation-bci-policy-tournas-johnson/. Accessed 2 Jul. 2023.
[60] "Time is running out to regulate neurotechnology - Science|Business." https://sciencebusiness.net/news/time-running-out-regulate-neurotechnology. Accessed 2 Jul. 2023.
[61] "Neurotechnology and the Law | August 2022." https://m-cacm.acm.org/magazines/2022/8/262912-neurotechnology-and-the-law/fulltext. Accessed 2 Jul. 2023.
[62] "OECD Recommendation on Responsible Innovation in ...." 11 Dec. 2019, https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm. Accessed 2 Jul. 2023.
[63] "Deep Brain Stimulation for Alzheimer's Disease - NCBI." 11 Mar. 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7990787/. Accessed 2 Jul. 2023.
[64] "The 3rd of all EU-r rights: Integrity and how the Charter contributes." 28 Jan. 2020, https://www.eurac.edu/en/blogs/eureka/the-3rd-of-all-eu-r-rights-integrity-and-how-the-charter-contributes. Accessed 2 Jul. 2023.

The Organization for Economic Co-operation and Development (OECD) adopted the *Recommendation on Responsible Innovation in Neurotechnology* in 2019, which provides a framework for how countries and institutions can practice ethical innovation within the field of neurotechnology. As an international organization with 38 member countries, the OECD has far-reaching influence on social and economic issues in the context of human rights. With the Recommendation, nine key principles lay the foundation for sustainable and ethical developments in neurotechnology, including promoting inclusivity and protecting personal neuro-data. Although non-binding, the Recommendation still provides important initial steps and guidelines in the ever-developing field of neurotechnology.[65] And similar frameworks proposed by similar international organizations will further strengthen worldwide efforts to create an ethical environment for neurotechnology. Moreover, with the support of ethicists and regulators such as the International Neuroethics Society, governments and the international community can better recognize challenges and potential remedies within neurotechnology.

[65] "New Frontiers of the Mind: Enabling responsible innovation in ...." 19 Dec. 2019, https://www.oecd-forum.org/posts/57641-new-frontiers-of-the-mind-enabling-responsible-innovation-in-neurotechnology. Accessed 2 Jul. 2023.