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INSTITUTE OF NEUROETHICS

Towards Inclusive EU Governance of Neurotechnologies

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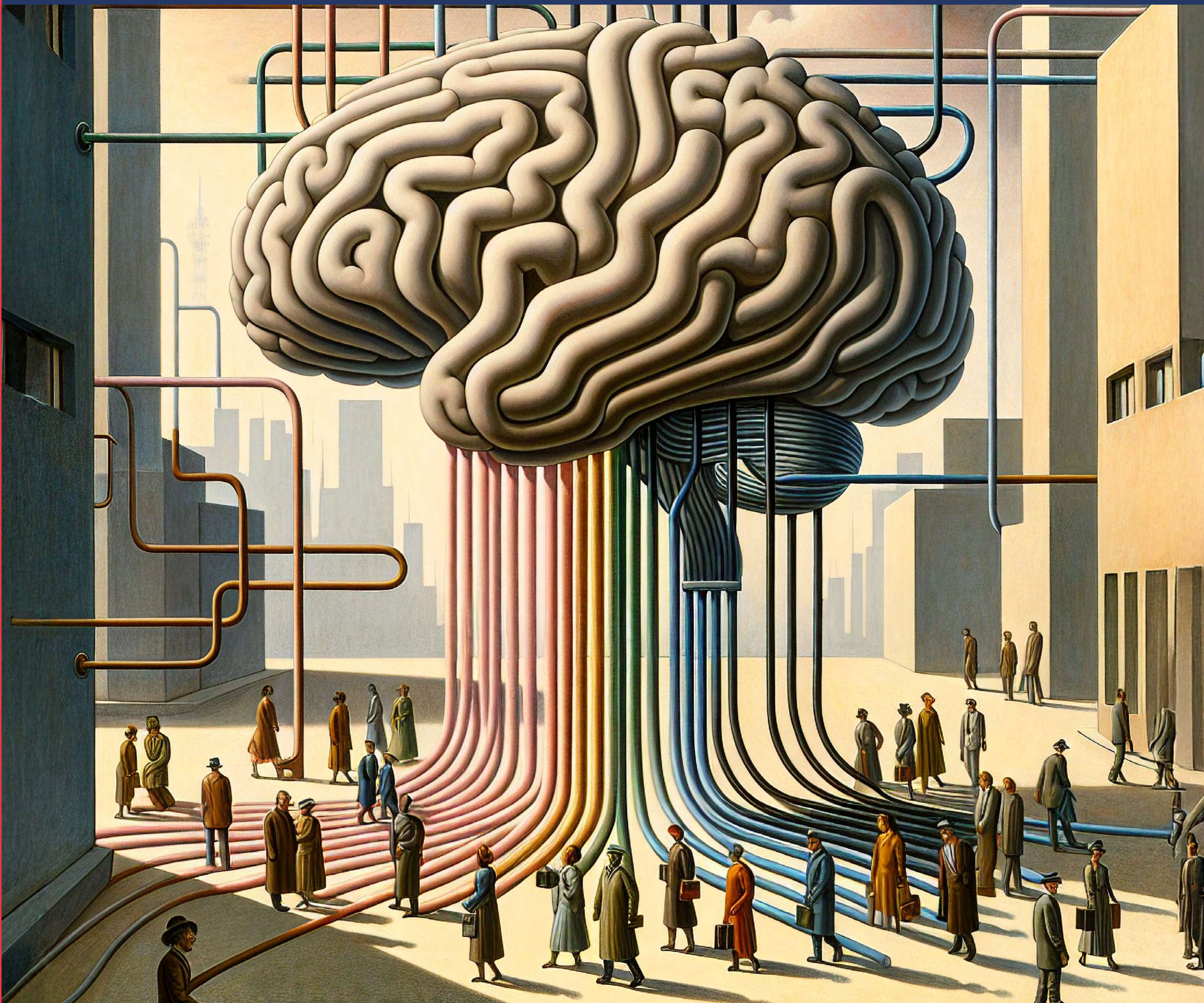

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Executive summary

As neurotechnologies continue to rapidly evolve, their transformative potential across research, clinical, and consumer applications makes it imperative to address both their ethical dimensions and societal impacts, and to create robust governance frameworks that put the needs of individuals at the forefront of this emerging field.

Neurotechnologies raise a range of ethical issues, from those related to safety, transparency, privacy, and informed consent, to their impact on users' autonomy and agency, as well as their potential for misuse. Moreover, they are fraught with ambiguities concerning both their classification (for example, the distinction between invasive and non-invasive is increasingly unclear) and application (they can shift from wellness applications to medical insights, for example, blurring the line between medical and non medical usage). These ambiguities make them particularly complex to regulate.

Drawing on an extensive literature review, sustained interaction with experts across various disciplines and contexts, and the outcomes of two workshops jointly organised by ICFG and IoNx, this discussion paper argues for the need for neurotechnology governance frameworks that are adaptive, conceptually sound, inclusive, and anticipatory. We provide a description of the ethical issues raised by neurotechnology and an analysis of key conceptual grey areas. Then, we turn to governance, presenting a case study and four scenarios to show that existing fragmented

This discussion paper argues for the need for neurotechnology governance frameworks that are adaptive, conceptually sound, inclusive, and anticipatory.

regulatory frameworks are insufficient to keep pace with the rapid advancements and expanding applications of these technologies.

We conclude with the following recommendations for EU neurotechnology governance:

1. **Anticipatory policymaking: fostering safe innovation and use through forward-looking policy.** Keeping up with the rapid pace of innovation in the field of neurotechnology requires good foresight. Anticipatory governance enables policymakers to design more adaptive and future-proof regulations that can respond to future developments. Furthermore, by proactively evaluating potential risks and opportunities, the EU can target investments in technologies that not only advance innovation but also uphold ethical and regulatory standards. This proactive approach could support a sustainable ecosystem for neurotechnology, positioning the EU as a leader in neurotechnology while safeguarding the public and upholding trust and societal values.

2. **Inclusive and participatory policymaking: building trust and democratic legitimacy through meaningful stakeholder engagement.** Leveraging the full toolbox of participatory mechanisms for broad public engagement will strengthen transparency and public trust in neurotechnology and its governance. Involving a broad range of stakeholders, including scientists, industry leaders, ethicists, patients, and the general public, supports a collaborative process where societal values and concerns are embedded into policy frameworks, enhancing their responsiveness to society's needs and their alignment with societal values.

3. **Clear and harmonised policymaking: frame concepts responsibly and illuminate grey areas.** Responsible conceptualisation would promote clarity and consistency across jurisdictions, reducing regulatory fragmentation and making it easier for innovators to comply with standards. It would also enable ethical alignment and the protection of fundamental rights like privacy and autonomy, no matter where the technologies are developed or used. Additionally, it would support cross-border collaboration and foster a thriving European neurotechnology ecosystem through a genuine Single Market, reinforcing the EU's leadership in this rapidly evolving field.

Introduction

Europe is facing a rising burden of brain disorders. An aging population is resulting in an increase in the incidence, prevalence, disability and overall economic burden linked to neurological age-related conditions,[1] while a mental health crisis is impacting younger generations.[2] Beyond the physical and emotional toll on patients and caretakers, the global annual healthcare expenditures for neurological disorders is estimated to be over USD 1 Trillion and increasing at a rate of 3%+ yearly.[3] European stakeholders are increasingly raising urgent calls for effective prevention, diagnosis, and treatment strategies for neurological disorders.[4,5]

In recent years, brain research has significantly progressed due to advancements in abilities to measure, analyze, and interpret data from the brain. Further, the convergence of brain technology with AI, data analytics, engineering, biomedical sciences, and computer science has propelled neuroscience forward. Significant public and private investment towards advancing fundamental understanding of human brain function to address pressing medical challenges has promoted an era of high-quality research, multidisciplinary collaboration, and translation into practical applications.[6] Many experts believe we are standing at the beginning of a surge in neuroscience innovation, driven especially by advances in neurotechnologies.[7]

Neurotechnologies are "devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural system of natural persons."[8] They hold significant promise for advancing research, and improving and supporting brain and mental health, well-being, healthy neurodevelopment and healthy ageing. Neurotechnologies offer transformative effects on people's lives, from enabling movement in patients with Parkinson's disease to experimental interventions that restore communication on patients who have lost the ability to speak.

[1] Deuschl G, et al, The burden of neurological diseases in Europe: an analysis for the Global Burden of Disease Study 2017, The Lancet Public Health, 2020.

[2] OECD/European Union, "Coping with COVID-19: Young people's health in an age of disruption", in Health at a Glance: Europe 2022: State of Health in the EU Cycle, OECD Publishing, 2022.

[3] Mitchell A, et al, Estimating the Economic Impact of Direct Health Expenditure on Brain Disorders, Globally and in the United States, Neurology, 2024.

[4] European Brain Council, Joint Letter: "Urgent Call to Action: A Place for Brain Health at the Top of EU Policy Agendas," 2024.

[5] ERA-NET NEURON.

[6] Amunts K, et al. The coming decade of digital brain research: A vision for neuroscience at the intersection of technology and computing. Imaging Neuroscience, 2024.

[7] Neuroscience and Society: A Life Course Approach to Brain Health – Science Summit of 79th United Nations General Assembly, 2024.

[8] Garden H, et al, "Responsible innovation in neurotechnology enterprises", OECD Science, Technology and Industry Working Papers, No. 2019/05, OECD Publishing, 2019.

Today, neurotechnologies are being used to restore movement in individuals who have been paralysed. Their potential is being explored for restoring communication abilities in those who cannot speak, enabling them to converse in their native language using their own voice through an avatar.[9] Additionally, researchers are not only focusing on diagnosis but also on prediction of diseases before their onset,[10] paving the way for preventative measures or interventions to slow disease progression.

Some neurotechnologies are designed to collect and monitor brain data (record and decode brain activity), others to modulate (alter brain activity) and others (bidirectional) to do both. Neurotechnologies often interface with the brain in a variety of ways. A distinction is typically made between invasive neurotechnologies – requiring surgery to implant devices or electrodes – and non-invasive ones that interact with the brain and nervous system through the skull or skin, such as wearable technologies.

Originally developed for clinical, healthcare, and brain research purposes, neurotechnologies are also now being explored for their potential to enhance human capacities, such as improving memory, augmenting sensory perception, and enhancing cognitive abilities.[11] While historically, cognitive enhancement has been achieved through pharmaceuticals, neurotechnologies are emerging as alternatives, leading to significant private sector investments in consumer products for wellness, gaming, and even workplace applications. Wearable devices, known as consumer neurotechnologies, are marketed for non-medical purposes like improving focus, meditation, and sleep, raising important concerns around transparency, privacy, and agency, especially as their use extends beyond the clinical domain to everyday life.

Researchers are not only focusing on diagnosis but also on prediction of diseases before their onset, paving the way for preventative measures or interventions to slow disease progression.

Consumer neurotechnologies have the potential to reach a wide market of non-medical consumers; tech giants like Meta and Apple, as well as many other companies, are developing and patenting consumer products that would allow people to interact with computers directly via their nervous system. Some wearable neurotechnologies are already available to consumers for wellness, education, and in the workplace.

Private investment in neurotechnologies is surging. A UNESCO report highlights a 22-fold increase in investment from 2010 to 2020, with funding reaching $7.3 billion in 2020 and totaling $33.2 billion over that decade.[12] This growth has understandably sparked policy conversations about the adequacy of existing ethical, legal, and governance tools as they apply to neurotechnologies, particularly in non-medical contexts.

[9] Matisko A, Bilingual speech neuroprosthesis, Science Robotics, 2024.

[10] Ahlgrim NS, Garza K, Hoffman C, Rommelfanger KS, Prodromes and Preclinical Detection of Brain Diseases: Surveying the Ethical Landscape of Predicting Brain Health, eNeuro, 2019.

[11] Valeriani D, Santoro F, Ienca M, The present and future of neural interfaces, Frontiers in Neurorobotics, 2022.

[12] Hain, DS, et al, Unveiling the neurotechnology landscape: Scientific advancements, innovations and major trends, UNESCO, 2023.

This discussion paper integrates contributions and insights from various communities committed to advancing the field in a responsible manner. It draws on an extensive literature review, sustained interaction with experts across various disciplines and contexts, and the outcomes of two workshops jointly organised by ICFG and IoNx.[13] We conclude by offering actionable recommendations to foster a safe and responsible neurotechnology ecosystem that benefits society, based on the tenets of anticipatory and participatory governance.

[13] The first workshop, "Future Governance of Neurotechnology: What Role for the EU?" took place in Brussels in February 2024. The second, "Toward an Inclusive Governance Approach to Neurotechnology in the EU" was held in Brussels in May 2024. Both events brought together diverse participants including researchers, academics, policymakers, funders, technology developers, and members of various international organisations.

Ethics of Neurotechnology

The ethical dimension of neurotechnologies

Neurotechnologies are primarily developed and deployed to advance knowledge of the brain to promote the health and wellbeing of human beings. However, the design, development, and deployment of neurotechnologies is not ethically neutral. As medical and non-medical neurotech devices have left the laboratory, unexpected challenges and threats to patient dignity, autonomy, and agency as well as privacy have emerged.

To illustrate, electroencephalography (EEG), a century-old technology widely used in research and clinical settings, remains insufficiently optimised for people of African descent.[14] Furthermore, decisions about the use and users of neuroscientific products have ethical and societal implications. For example, wellness neurotechnologies designed for personal monitoring of stress and improving focus could also be used by employers for productivity surveillance.[15]

Notably the intersection of neurotechnology and AI ethics remains underexplored, but could benefit from shared insights and learnings.

Moreover, the extensive data processing that neurotechnologies require and their convergence with artificial intelligence,[16,17] can add layers to its ethical dimensions and exacerbate potential impacts on individuals, communities, and society, particularly regarding privacy and autonomy. AI ethics alone is an area of rich debate, with over 200 sets of ethics guidelines.[18] Notably the intersection of neurotechnology and AI ethics remains underexplored, but could benefit from shared insights and learnings.[19]

[14] Taylor L, Rommelfanger KS, Mitigating white Western individualistic bias and creating more inclusive neuroscience, Nat Rev Neurosci, 2022.

[15] Mathews D, et al., Neurotechnology and Noninvasive Neuromodulation: Case Study for Understanding and Anticipating Emerging Science and Technology, NAM Perspect, 2023.

[16] van Stuijvenberg, OC, et al., Developer perspectives on the ethics of AI-driven neural implants: a qualitative study, Sci Rep 14, 2024.

[17] Berger SE, Rossi F, AI and Neurotechnology: Learning from AI Ethics to Address an Expanded Ethics Landscape, Communications of the ACM, 2023.

[18] Kluge Corrêa N, et al, Worldwide AI ethics: A review of 200 guidelines and recommendations for AI governance, Patterns, 2023.

[19] Salles A, Farisco M, Neuroethics and AI ethics: a proposal for collaboration, BMC Neurosci25, 2024.

At present there are robust and thriving reflections on the ethics of neurotechnology as well as several attempts to develop guidelines and regulation to ensure its responsible design, development, and deployment.[20,21,22] Current regulatory frameworks for neurotechnology, however, are fragmented, non-specific, and often struggle to keep up with rapid advancements of neurotechnology.[23,24,25]

Additionally, there have been growing calls for the establishment of "neuro-rights:" advocating for revisions to human rights laws or the introduction of new rights to address emerging challenges raised by neurotechnologies.[26,27,28] Recently there has been a focus on reforming existing regulations to improve privacy protections in the consumer sector. Ethics and policy scholars have highlighted the need to engage both the private sector and the general public who have thus far been largely absent from these discussions.[29,30,31]

If guardrails are to be put in place to promote human wellbeing, it is necessary to understand the core ethical concerns that neurotechnologies raise. These include, but are not limited to those described below.

Ethical issues *in how neurotechnology works*

Safety: By interacting directly with the brain and nervous system, neurotechnologies pose potential safety risks including unintended side effects and long-term health impacts. While medical device regulation may in theory address some of these concerns through rigorous testing and clinical trials, there is largely a lack of standardisation in engineering across devices created to interface with the brain, particularly around addressing critical user needs and performance assessment.[32] Standards are especially lacking in consumer oriented neurotechnologies at the basic levels of efficacy and safety.[33,34] In addition, safety considerations related to the application of brain interventions can lead to atypical safety concerns related to unwanted alterations to identity, agency, and autonomy,[35] described in more detail below.

[20] O'Shaughnessy MR, et al., Neuroethics guidance documents: principles, analysis, and implementation strategies, J Law Biosci, 2023.

[21] Bublitz JC, What an International Declaration on Neurotechnologies and Human Rights Could Look like: Ideas, Suggestions, Desiderata, AJOB Neuroscience, 2023.

[22] Goering S, Klein, E, Specker Sullivan L, et al., Recommendations for Responsible Development and Application of Neurotechnologies, Neuroethics, 2021.

[23] Marchant G. The Growing Gap Between Emerging Technologies and the Law. In: The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight. The International Library of Ethics, Law and Technology, 2011.

[24] Johnson W, Catching Up with Convergence: Strategies for Bringing Together the Fragmented Regulatory Governance of Brain-Machine Interfaces in the United States, 30 Annals Health L., 2021.

[25] Rommelfanger KS, Pustilnik A, Salles, Mind the Gap: A Lessons learned from Neurorights, AAAS Science and Diplomacy, 2022.

[26] Sententia W, Neuroethical considerations: cognitive liberty and converging technologies for improving human cognition. Ann N Y Acad Sci, 2004.

[27] Yuste R, Genser J, and Herrmann S, It's Time for Neuro-Rights: New Human Rights for the Age of Neurotechnology, Horizons, 2021.

[28] Ienca M, Andorno R, Towards new human rights in the age of neuroscience and neurotechnology, Life Sci Soc Policy, 2017.

[29] Rommelfanger KS, Pustilnik A, Salles, Mind the Gap: A Lessons learned from Neurorights, AAAS Science and Diplomacy, 2022.

[30] Pfotenhauer SM, et al., Mobilizing the private sector for responsible innovation in neurotechnology. Nat Biotechnol, 2021.

[31] MacDuffie KE, Ransom S, Klein E, Neuroethics Inside and Out: A Comparative Survey of Neural Device Industry Representatives and the General Public on Ethical Issues and Principles in Neurotechnology, AJOB Neurosci, 2022.

[32] Standards Roadmap: Neurotechnologies for Brain-Machine Interfacing, IEEE SA Industry Connections Activity, 2020.

[33] Ienca M, Haselager P, Emanuel EJ, Brain leaks and consumer neurotechnology, Nat Biotechnol, 2018.

[34] Neurotech Evidence Book, Internet of Brains, 2023.

[35] https://pubmed.ncbi.nlm.nih.gov/30541767/

Transparency: Neurotechnologies involve complex data flows,[36] and users might be misled regarding when and how they are operating, which parameters are being used, and how and what data is collected, analysed, and interpreted. Providing clear, accessible, and honest descriptions of the relevant neurotech and how neural data is managed, including its limitations and justifications, is key to maintaining public trust and understanding.[37] However, considering that most signals in our nervous system operate unconsciously and beyond our awareness or control, it might be technically difficult to accurately identify the types of data that neurotechnology collects and interprets, and thus the necessary transparency might be difficult to achieve.

Privacy: The collection and inferences drawn from brain data create complicated privacy issues. Neurotechnologies rely on collecting and analysing extensive neurodata (gathered from the brain and nervous system) often leveraging the use of AI algorithms to enhance effectiveness. This process increases the risk of sensitive information being exposed, misused or used without proper consent.[38] There are particular concerns surrounding "mental privacy" and the right to freedom of thought, particularly in relation to non-consensual interpretations[39] of brain activity and mental data.[40] These concerns go beyond the raw data itself: they include the types of inferences that can be made about an individual's preferences, behaviors, and even future brain health status.[41]

DID YOU KNOW THAT...?

A recent preliminary study involving 7 participants demonstrated that non-invasive neurotechnology (fMRI) can decode imagined images and words, producing intelligible word sequences that capture the meaning of perceived and imagined speech, as well as silent videos.[42] A more recent study from researchers at Meta's AI unit, utilised EEG on 175 volunteers to show that neurotechnology in laboratory settings can decode which words and sentences participants are currently listening to.[43] These studies further exacerbate concerns about the extent to which neurotechnology might provide insights into people's thoughts, perceptions, and emotions.

[36] Berrick D, Brain-Computer Interfaces & Data Protection: Understanding the Technology and Data Flows, Future of Privacy Forum, 2022.

[37] Bublitz JC, What an International Declaration on Neurotechnologies and Human Rights Could Look like: Ideas, Suggestions, Desiderata, AJOB Neuroscience, 2023.

[38] Eke D, et al., International data governance for neuroscience, Neuron, 2022.

[39] Ligthart S, Freedom of thought in Europe: do advances in 'brain-reading' technology call for revision?, J Law Biosci, 2020.

[40] Ienca M, Malgieri G, Mental data protection and the GDPR, J Law Biosci, 2022.

[41] Jwa AS, Poldrack RA, Addressing privacy risk in neuroscience data: from data protection to harm prevention, Journal of Law and the Biosciences, 2022.

[42] Tang J, et al., Semantic reconstruction of continuous language from non-invasive brain recordings. Nat Neurosci 26, 2023.

[43] Défossez A, Caucheteux C, Rapin J, et al., Decoding speech perception from non-invasive brain recordings, Nat Mach Intell 5, (2023).

Bias: The presence of bias in the development, discovery, and interpretation of neurotechnology is widely acknowledged.[44] Neurotechnologies are often based on analysis of datasets from homogeneous populations and training samples, which can skew research goals, interpretations, and assessment, while possibly leading to exclusion or misrepresentation of minority and vulnerable populations.[45] Moreover, biased data may affect what is considered "normal" brain function. The risk of bias is exacerbated by the use of AI, due to the data used to train algorithms: if training data includes historical biases related to gender, race, culture, or other factors, the algorithm - and neurotechnology - can learn and operate along these biases.[46,47,48] Additionally, if certain groups are underrepresented in the data, the algorithm may not perform accurately for those groups.[49] Claims about insights into the brain often touch on fundamental qualities about an individual's mental capacity, emotional processing, predilections, decision-making and identity. As a result, bias in neurotechnology can be potentially more serious, given the nature of the scientific claims made about the nature of individuals and societies.[50]

Ethical issues *in the individual and societal impacts of neurotechnologies*

Access: Like most emerging technologies, neurotechnologies are developed and deployed within a status quo market environment that lends itself to disparities in affordability, access and potential further exacerbation of socio-economic imbalances. While ensuring equal access to neurotechnologies and their benefits is crucial, achieving this in practice is challenging and requires careful consideration of social, cultural, and economic factors.

Discrimination and stigma: The practical impacts of biased data or biased interpretations of neurotypicality and "difference" can perpetuate and exacerbate inequalities, discrimination and stigma, both at the individual and group level. Concerns emerge even when not based on biased information, particularly in non-clinical settings such as the workplace to monitor performance or enhance productivity,[51] or if social norms or academic competition pressures people to use neurotechnologies.

Identity: Our brains are intimately connected to our identities and sense of self. While altering brain activity to produce a change in a person's cognitive and affective states is not novel or unique to neurotechnology, these technologies can be more precise and create changes relatively quickly. Such interventions can lead to potential unwanted alterations to personalities, thoughts, and even

[44] Goering S, et al., Recommendations for Responsible Development and Application of Neurotechnologies, Neuroethics 14, 2021.

[45] Beery AK, Zucker I, Sex bias in neuroscience and biomedical research, Neurosci Biobehav Rev, 2011.

[46] Berger SE, Rossi F, AI and Neurotechnology: Learning from AI Ethics to Address an Expanded Ethics Landscape, Communications of the ACM, 2023.

[47] Bias in Algorithms: Artificial Intelligence and Discrimination, Fundamental Rights Agency, 2022.

[48] Larrazabal AJ, et al., Gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis, Proc Natl Acad Sci, 2020.

[49] Farisco M, et al., A method for the ethical analysis of brain-inspired AI, Artif Intell Rev 57, 2024.

[50] Choudhury S, Nagel S, Slaby, J, Critical Neuroscience: Linking Neuroscience and Society through Critical Practice, BioSocieties, 2009.

[51] Muhl E, Andorno R, Neurosurveillance in the workplace: do employers have the right to monitor employees' minds? Frontiers in Human Dynamics, 2023.

If a device can modulate brain activity, enhance cognitive functions, or even predict and influence behavior, individuals might wonder whether their decisions are truly their own.

to how humans understand themselves. Moreover, technologies like eye tracking as a proxy of brain development in infants and degeneration in adults are used to predict the development of autism[52] and onset of Alzheimer's.[53] However, a prediction of a brain disorder, whether accurate or not, may be seen as forecasting who the person might become, which can have a significant impact on their overall quality of life.

Agency and Autonomy: Neurotechnology might raise concerns about the extent to which the user remains in control of their thoughts and actions. If a device can modulate brain activity, enhance cognitive functions, or even predict and influence behaviour, individuals might wonder whether their decisions are truly their own or whether they are being shaped by external technological influences. This uncertainty can lead to a diminished sense of personal agency and confusion about a sense of responsibility, as well as a lack of trust in the devices.

For example, restorative neurotechnologies can empower patient autonomy. For example, patients experiencing blindness have regained partial vision through a commercial retinal implant. However, when the company manufacturing the implant was acquired, the device was discontinued leaving patients at risk of losing their sight again.[54,55] In cases like this, patients' autonomy becomes compromised. Patients are thus forced to bear the burdens of long-term responsibilities of maintaining outdated or discontinued implanted devices.

DID YOU KNOW THAT...?

With approximately 200,000 patients implanted worldwide, deep brain stimulation (DBS)[56] has offered enormous relief for Parkinson's disease, an incurable debilitating movement disorder. However, a small percentage of patients implanted with stimulating electrodes to treat Parkinsonism (DBS) have experienced severe mania.[57] This case indicates that implanted stimulation can raise issues beyond identity, impacting the implanted individual's agency. Other studies note that a few individuals undergoing DBS with this same treatment reported feeling "like an electric doll" and not in control.[58,59]

[52] Sarrett JC, Rommelfanger KS, Commentary: Attention to Eyes Is Present but in Decline in 2-6-Month-Old Infants Later Diagnosed with Autism, Front Public Health, 2015.

[53] Ahlgrim NS, Garza K, Hoffman C, Rommelfanger KS, Prodromes and Preclinical Detection of Brain Diseases: Surveying the Ethical Landscape of Predicting Brain Health, eNeuro, 2019.

[54] Okun MS, et al., Definition of Implanted Neurological Device Abandonment: A Systematic Review and Consensus Statement, JAMA Netw Open, 2024.

[55] Strickland E, Harris M, Their Bionic Eyes are now Obsolete and Unsupported, 2022.

[56] Lee DJ, et al., Current and future directions of deep brain stimulation for neurological and psychiatric disorders, J Neurosurg, 2019.

[57] Leentjens AF, Depression in Parkinson's disease: conceptual issues and clinical challenges, J Geriatr Psychiatry Neurol, 2004.

[58] Schüpbach M, et al., Neurosurgery in Parkinson disease: a distressed mind in a repaired body? Neurology, 2006.

[59] Agid Y, et al., Neurosurgery in Parkinson's disease: The doctor is happy, the patient less so? Journal of Neural Transmission, 2006.

Ethical issues *related to ethical-legal processes*

Informed consent is a legal tool designed to promote respect and protection of an individual's human dignity, and in so doing, enhancing their autonomy and agency.

- **In the clinic:** As with any therapeutic intervention, obtaining the patient's informed consent (provided that the patient has the capacity to do so) is essential before any neurotechnological intervention. However, some interventions might affect a person's capacity to give or continue giving consent - either narrowing or broadening it.[60] Changes in decision-making capacity challenge the presumption that current processes for consent are adequate for medical interventions in general, especially when neurotechnologies that might aim to change traits or behaviors central to the person are involved.
- **By consumers:** The complexity and lack of transparency in neurotechnologies can prevent users' ability to make fully informed decisions. This presents a challenge as existing legal language, such as that in the GDPR on informed consent,[61] which may be inadequate to address evolving ethical and human rights concerns that might be uniquely raised by neurotechnology. To illustrate:
    - **Future use of data:** It is also unclear how brain data might be used in the future: as data analyses become more sophisticated and neurodata is increasingly combined with other types of personal data, it is likely that new, previously unattainable insights about individuals might emerge.
    - **Re-identifying data:** Furthermore, even if the data is anonymised - as most current-day consumer neurotechnologies companies promise to do in their terms and conditions - the data donor could still be re-identified from combined data with other data sets[62] and future analyses,[63] to which they did not originally consent.

An ethical responsibility becomes a legal obligation through legal instruments. When it comes to neurotechnology there are significant areas of debate.

- **Proportional protection of brain data:** For example, the GDPR calls for an obligation to protect a human right to privacy and requires specific actors to take on proportional responsibility for data that is deemed socially as sensitive. However, the social value of data derived from the brain may evolve as scientific capabilities to collect, process, and interpret insights about groups and individuals from these data continue to advance (discussed further in Section III.4).[64]

[60] Willyard C, The tricky ethics of brain implants and informed consent, MIT Technology Review, 2023.

[61] Consent, GDPR.

[62] Klonovs CK, et al., "ID Proof on the Go: Development of a Mobile EEG-Based Biometric Authentication System," in IEEE Vehicular Technology Magazine, 2013.

[63] Jwa AS, Koyejo O, Poldrack RA, Demystifying the likelihood of reidentification in neuroimaging data: A technical and regulatory analysis, Imaging Neuroscience, 2024.

[64] Jwa AS, Poldrack RA, Addressing privacy risk in neuroscience data: from data protection to harm prevention, Journal of Law and the Biosciences, 2022.

- **Abandonment:** As described above, patients with retinal implants were faced with the prospect of blindness when their implant was discontinued. There currently is no standard for responsibilities when it comes to long-term maintenance of implanted devices.[65] In addition, a recent consensus report highlights the urgency for clear guidance given the rapid growth of the neurotechnology market, the increasing commercial availability of these devices, and the potential for implanted devices to become obsolete or incompatible with newer models.[66]

DID YOU KNOW THAT...?

Informed consent alone may not be sufficient for protecting human rights. For instance in Chile, Guido Girardi, the Senator who led the introduction of a 2021 amendment to the Chilean Constitution to protect mental integrity, decided to put the new amendment to the test. He purchased a consumer wearable brain sensing device and consented to a policy that allowed the company to collect, process, and essentially own his brain data. However, when he tried to gain access to his personal data, he was unable to do so because he did not have a paid subscription. Senator Girardi filed a lawsuit against the company largely on the basis of threats to his privacy and won, requiring the company to delete his data.[67] This case illustrates that informed consent, even if given, was insufficient to protect his rights. While the Senator claimed that his neurorights had been violated, the Court's decision in his favour was ultimately based on a thorough consideration of Chile's constitutional and national laws and international human rights instruments such as the UN Declaration of Human Rights among others.[68]

Ethical issues *related to uses and misuses of neurotechnology*

Off-label usage: Applications of neurotech that mimic medical uses but have not passed rigorous clinical trials pose a significant ethical issue, as they can mislead users especially when they do not function as expected or claimed. This can lead to harm if users rely on ineffective or unsafe technologies instead of clinically validated treatments.

Workplace/performance monitoring: The use of neurotechnology into workplaces or educational settings for the purpose of monitoring attention and performance raises profound ethical concerns, as individuals may feel pressured to comply with monitoring to enhance productivity or academic performance.[69] This can infringe on personal autonomy, lead to surveillance culture, and impact well-being by

[65] Hendriks S, et al., Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research With Neural Devices: A Review, JAMA Neurol, 2019.

[66] Okun MS, et al., Definition of Implanted Neurological Device Abandonment: A Systematic Review and Consensus Statement, JAMA Netw Open, 2024.

[67] Cornejo-Plaza MI, Cippitani R, Pasquino V, Chilean Supreme Court ruling on the protection of brain activity: neurorights, personal data protection, and neurodata, Front Psychol, 2024.

[68] Carter H, Neural Rights: Landmark Ruling, ArentFox Schiff, 2023.

[69] Muhl E, Andorno R, Neurosurveillance in the workplace: do employers have the right to monitor employees' minds? Frontiers in Human Dynamics, 2023.

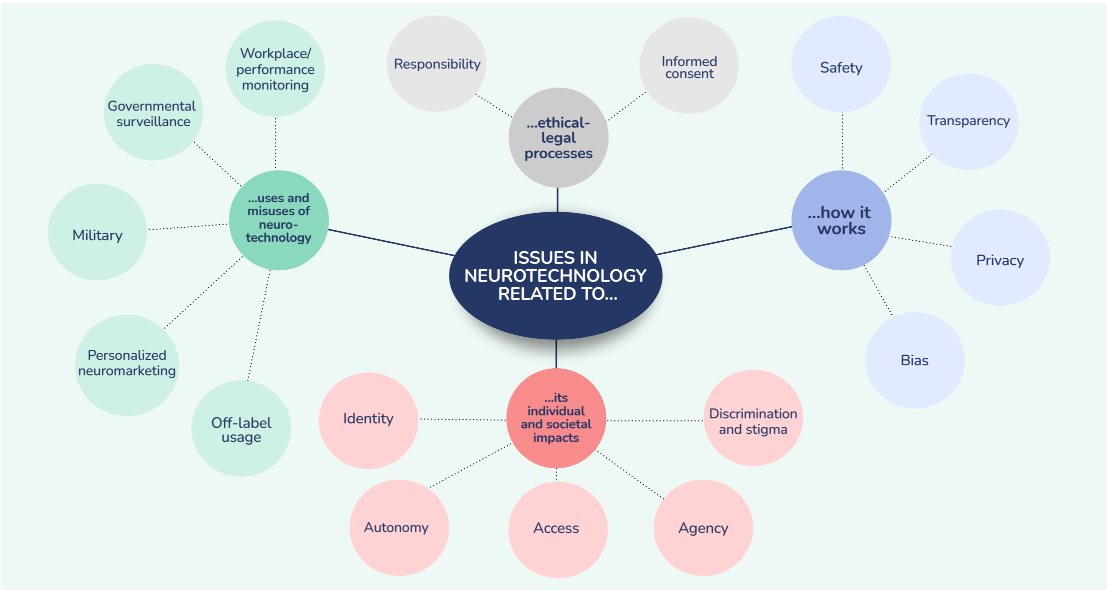
creating stress and anxiety over constant monitoring, and risks violating privacy and the rights of individuals (particularly children), as tracking cognitive states can reveal deeply personal information. It also has unknown long-term consequences for the neurodevelopment of young people in education.[70]

Governmental monitoring: The possibility of governmental monitoring or manipulation using neurotechnology raises ethical concerns,[71] especially regarding the extraction of information or manipulation of individuals' behaviour, potentially without their consent. Even if consent is given, there is the risk of coercion or lack of full understanding by individuals about how their brain data is used, which could result in violations of personal freedoms. Additionally, neurotechnology could be exploited for malicious purposes such as influencing public opinion, conducting surveillance, or modifying behaviour in marketing or political campaigns.

Personalised neuromarketing: Today, corporations already use personal data[72] – as well as data on how people interact with platforms[73] – to build people's profiles and drive content algorithms on social media. The ability to monitor and interpret brain activity of users through wearable consumer neurotechnology devices could allow tech companies to gain unprecedented insights into consumers' thoughts, preferences, and vulnerabilities. That would propel the era of big data analytics and surveillance capitalism to new heights, as well as furthering the political polarisation effect of algorithm-driven online echo chambers.[74]

Military: One ethically complex use of neurotechnology is its dual use in the military domain,[75] where it could be employed in intelligence operations, or even enhancing soldier performance. Neurotech could further be weaponised to manipulate

Figure 1: Summary of Ethical Issues Raised by Neurotechnology



[70] Neurotechnology and Children Working Paper, UNICEF, 2024.

[71] Lavery, T. et al., Neuro-Nudging and Predictive Models: Adaptive Ethics for Behavioural Science in a Changing World, In: The Behavioural Economics Guide, 2024.

[72] Goswami S, What Does Big Tech Actually Do With Your Data? Forbes, 2022.

[73] Shieber J, Meet the tech company that wants to make you even more addicted to your phone, TechCrunch, 2017.

[74] Bentzen N, Strategic and systemic threats to the democratic information sphere, In: Future Shocks 2023, European Parliamentary Research Service, 2023.

[75] Aicardi C, et al. Opinion on 'responsible Dual Use' Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology, Zenodo, 2021.

the mental states of adversaries or be used for neurological interrogation to extract information against individuals' will. The ethical implications include the loss of personal autonomy, the invasion of privacy, and the potential for lasting psychological harm. Additionally, military applications blur the line between defensive and offensive use, raising concerns about long-term impacts on both combatants and civilians.[76]

DID YOU KNOW THAT...?

Wearable brain sensing headsets have been used to track the stress and awareness levels of school children[77] and employees,[78] raising public concerns about mental privacy, power dynamics, and who should have access to information about peoples' brain states.

Conceptual grey areas

In addition to the ethical issues outlined above, certain conceptual grey areas plague the neurotechnology debate, often negatively impacting the ability for stakeholders to effectively establish robust guidelines and regulations, especially when not systematically addressed. Addressing them requires intentional and systematic exploration involving diverse communities (Recommendation 3). Below we highlight four of these conceptual grey areas that are central to our discussion in the following sections. This is not intended to be an exhaustive account, but rather a focused exploration of some key challenges for the purposes of the following sections.

Invasive and non-invasive neurotechnological devices.

Any device designed to affect the brain must interact with it in some way. However, the current language of invasive versus non-invasive neurotechnologies can be unclear. Importantly, these labels and the assumptions associated with them carry significant ethical implications

- **"Invasive"** methods, which involve surgically inserting components into the skull, pose physical risk, require trained expertise, and significant financial resources. While the precision that can be offered by implanted technologies makes them often preferable to non implanted ones, they carry inherent risks such as infection, bleeding, and potential damage to brain tissue.[79]
- **"Non-invasive"** methods, though at first glance appear relatively safer and less costly, can still result in direct impact on the structure and function of the brain with electrical current or other (such as magnetism or ultrasound[80]) passed through an intact skull. Further, non-invasive technologies can also collect highly

[76] Mantellassi F, In focus: The challenges of neurotechnology, Geneva Centre for Security Policy, 2022.

[77] Standaert M, Chinese primary school halts trial of device that monitors pupils' brainwaves, The Guardian, 2019.

[78] Ackerman E, Strickland E, Are you ready for workplace monitoring? IEEE, 2022.

[79] Hendriks S, et al., Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research With Neural Devices: A Review, JAMA Neurol, 2019.

[80] Yaakub SN, et al. Transcranial focused ultrasound-mediated neurochemical and functional connectivity changes in deep cortical regions in humans, Nat Commun, 2023.

sensitive information about a person's brain activity, including cognitive patterns, therefore raising significant privacy and ethical concerns. In short, "non-invasive" stimulating technologies can still have influence in both superficial and deep structures of the brain as well as its functioning.

- There are also categories referred to as **"minimally invasive,"** such as "electroceuticals." For example, injectable electronics could be activated wirelessly and externally without implantations or surgery.[81] Furthermore, over time, neurotechnologies are projected to become smaller, wireless, and less expensive in order for greater scaling and accessibility.[82]

Less invasive technologies are generally perceived as less ethically problematic, whereas more invasive ones, such as brain implants, are viewed as more ethically concerning due to the higher immediate health risks involved. Similar related assumptions are made regarding the reversibility of some devices' effects. To illustrate, there seems to be an assumption that the easy removal of an implanted device will have somehow more reversible effects. However, this thinking might leadto overly simplistic conclusions not just about risks but also about what reversibility means.[83]

The question then arises: is there a substantial moral difference between invasive and non-invasive methods beyond the obvious safety concerns associated with physically invasive procedures? This highlights underlying conceptual assumptions and muddiness regarding the notion of invasiveness[84] that need to be addressed in order to apply safety considerations in practice.

Medical and non medical neurotechnology

The distinction between medical and non-medical neurotechnology is often blurred both in terms of the technology and the data involved. For example, data from recreational brain sensing devices could be used to assess or predict trajectories of brain health,[85] while medical neurotechnologies can be effectively used in the development of consumer devices.

Neurotechnology companies could also grant consumer data access to medical companies, who could then repurpose those data to therapeutic product development.[86] This blurriness raises key tensions, such as the distinction between therapy (aimed at restoring function) and enhancement (aimed at improving a human function beyond the level possessed by the user before the device). To illustrate, is addressing typical age-related cognitive decline enhancement? One neurologist coined the term "cosmetic neurology" to refer to the potential evolving role of physicians to offer "quality of life" interventions.[87]

[81] Neely RM, et al., Recent advances in neural dust: towards a neural interface platform. Curr Opin Neurobiol, 2018.

[82] Gaudry KS, et al., Working Group on Brain-Interfacing Devices in 2040, Projections and the Potential Societal Impact of the Future of Neurotechnologies, Front Neurosci, 2021.

[83] Reversibility of the effects of invasive procedures such as DBS plays a key role in their ethical assessment. If the changes induced can be reversed, the procedure might be seen as less ethically troubling compared to others that cause permanent changes such as brain lesioning. Moreover, such reversibility would support the autonomy of patients by allowing them to change their minds after undergoing the procedure. Still, this is a contentious issue: at stake is whether DBS can genuinely be considered a "reversible" technology. Some argue that "reversibility" is not a one-dimensional concept and resist attempts to simplify the discussion by invoking reversibility and irreversibility without addressing descriptive and evaluative claims regarding its importance.

[84] Collins B, Klein E, Invasive Neurotechnology: A Study of the Concept of Invasiveness in Neuroethics, Neuroethics, 2023.

[85] Paek AY, Brantley JA, Evans BJ, Contreras-Vidal JL. Concerns in the Blurred Divisions between Medical and Consumer Neurotechnology. IEEE Syst J. 2021.

[86] Rainey S, An Anticipatory Approach to Ethico-Legal Implications of Future Neurotechnology. Sci Eng Ethics 30, 2024.

[87] Chatterjee A, Cosmetic neurology: the controversy over enhancing movement, mentation, and mood. Neurology. 2004.

The blurriness of the applications of these technologies also creates jurisdictional issues. Medical devices undergo rigorous testing and approval processes to ensure their safety and efficacy while non-medical neurotech devices may lack such standards for oversight. This can lead to unmet safety and efficacy considerations.[88,89] In medical settings, there are clear frameworks for liability and accountability, while direct-to-consumer (DTC) neurotechnologies are readily accessible to consumers without a prescription.

Evidence and hype

There is a significant amount of hype surrounding the capabilities of some neurotechnologies (for example, consumer brain-sensing headsets) noting that many claims remain unsubstantiated.[90] The prefix "neuro" can carry significant persuasive power[91,92,93] even in light of nonsensical claims: what is known as "neuroenchantment" highlights how claims or images of the brain can be particularly compelling as compared to other emerging technologies.[94] As in the case of the tensions above, lack of conceptual clarity often contributes to the hype[95] and creates both scientists' confusion and public misconceptions about the limitations of current neurotechnologies and what they can actually achieve.[96,97]

Empowerment and vulnerability

Neurotechnology holds the potential for empowering people by restoring lost abilities, improving the quality of life for individuals with neurological or neuropsychiatric disorders, and even enhancing cognitive functions. Some argue that the integration of neurotechnology in everyday life, such as wearable devices that monitor brain activity and stress levels, can promote well-being and personal development by providing real-time feedback and interventions. However, neurotechnologies can also exacerbate existing vulnerabilities, such as economic and social inequalities, and even create new ones, such as exposing people to new threats to autonomy and potential exploitation (including manipulation, coercion, surveillance).[98]

The existence of these grey areas adds layers of complexity to existing governance approaches and presents challenges to the task of creating relevant and implementable regulatory frameworks and ethical guidelines. These are explored in more detail in the following section.

[88] Kreitmair KV, Dimensions of Ethical Direct-to-Consumer Neurotechnologies, AJOB Neuroscience, 2019

[89] Wexler A, Reiner PB, Oversight of direct-to-consumer neurotechnologies. Science. 2019.

[90] Neurotech Evidence Book, Internet of Brains, 2023.

[91] Maia de Oliveira Wood G, The protection of mental privacy in the area of neuroscience: Societal, legal and ethical challenges. Scientific Foresight Unit, European Parliamentary Research Service, 2024.

[92] Bennett EM, McLaughlin PJ, Neuroscience explanations really do satisfy: A systematic review and meta-analysis of the seductive allure of neuroscience. Public Underst Sci. 2024.

[93] Lilienfeld, SO et al., Neurohype: A field guide to exaggerated brain-based claims. In: The Routledge handbook of neuroethics, Routledge/Taylor & Francis Group. 2018.

[94] Ali SS, Lifshitz M, Raz A. Empirical neuroenchantment: from reading minds to thinking critically. Front Hum Neurosci. 2014.

[95] Rommelfanger KS, Ramos KM, Salles A. Conceptual conundrums for neuroscience. Neuron. 2023

[96] Wexler A, Thibault R, Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications. J Cogn Enhanc, 2019.

[97] Gilbert F, Russo I. Mind-reading in AI and neurotechnology: evaluating claims, hype, and ethical implications for neurorights. AI Ethics, 2024.

[98] Farahany N. The Battle for Your Brain. St Martin's Publishing Group, 2023.

Governance of neurotechnologies

Ethical issues and grey areas impact neurotechnology governance

These ethical issues and conceptual grey areas outlined above underscore the need for closer public and policy-maker exploration and scrutiny of existing mechanisms to ensure that the technologies are developed and applied in ways that serve the best interests of society.

While a number of recommendations and guidelines have attempted to address the ethical issues (see OECD and UNESCO efforts), less attention has been given to conceptual grey areas. Given how rapidly these technologies are developing, a proactive, anticipatory, and inclusive approach would be most beneficial in order to navigate the grey areas in the governance of these technologies. A critical first step to strike the right balance in governance, avoiding both overly restrictive regulation and insufficient guidance, is raising awareness of where these grey areas are to be found and identifying who should be involved in addressing them.

Approaches to emerging technology governance

There are various approaches to governance of emerging technologies, each reflecting different ways to manage the complexities and uncertainties inherent in these innovations. Concepts around governance have evolved from traditional state-led, “command and control” regulations, to an understanding that power and influence are more nuanced. At present, governance is increasingly shaped by "‘hybrid institutional complexes’ comprising heterogeneous interstate, infra-state, public–private and private transnational institutions, formal and informal.”[99] Within this landscape, while state law and regulation remain significant, there is room for flexible non-legal sources of influence, for example, soft law guidance from industry, non-governmental organisations (NGOs), and standards organisations. For instance, the OECD Framework for Anticipatory Governance of Emerging Technologies proposed a framework that covers the definition and implementation of guiding values, such as catering for the public good, or ensuring safety and security, oversight, stakeholder engagement, agile regulation and international cooperation.

[99] Abbott KW, Faude B, Hybrid institutional complexes in global governance. The Review of International Organizations, 2022.

Hard law processes can offer certainty and predictability to both states and individuals, ensuring legitimacy, accountability, and enforceability. However, the process of creating and enacting hard law is often slow whereas the pace of technological development is fast, also referred to as "the pacing problem"[100] Consequently, hard laws can quickly become outdated as technology evolves, and their applicability is jurisdictionally limited. This is where soft law can serve as a complementary approach. Soft law generally can be implemented faster than hard laws, with more inclusive stakeholder involvement, can offer flexibility and adaptability and can transition to become 'hard laws' over time. Soft law can play a crucial role in the development of both international and domestic norms. However, because soft law is often voluntary, it can lack democratic legitimacy, and can be associated with practices like ethics washing.[101] Experts often suggest a combined approach using both hard and soft law mechanisms to address technological challenges (see Recommendation 3.2).[102,103] As it has been noted, the EU has been exploring complementary approaches to governance since 2001.[104]

International governance of neurotechnology

For the reasons described above, several international organisations have so far turned to soft law as a first step to guide responsible innovation, outlining recommendations for policy action (including hard law) to be taken by Member States. The OECD has adopted the Recommendation on Responsible Innovation in Neurotechnology, the first international standard in ethical neurotechnology practices. UNESCO has produced a collection of essays on the risks and challenges of neurotechnologies for human rights,[105] and has also appointed an ad-hoc expert group to establish a comprehensive framework to address the challenges of neurotechnologies, that will culminate in a UN Recommendation on Ethics of Neurotechnology. In 2023, the Spanish Presidency of the Council of the EU led the adoption of the León Declaration on human-centric European neurotechnology.

Several international organisations have so far turned to soft law as a first step to guide responsible innovation, outlining recommendations for policy action (including hard law) to be taken by Member States.

Even if some argue that the rights already enshrined in broader intergovernmental documents (such as the European Convention on Human Rights and the Charter of Fundamental Rights of the European Union) make newly proposed "neuro-rights" in Europe redundant,[106] the need to promote responsible neurotechnological innovation remains. This imperative continues to demand the attention of European institutions,[107,108] and the

[100] Marchant G, Addressing the Pacing Problem, In: The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight, The International Library of Ethics, Law and Technology. 2011.

[101] Floridi L, Translating Principles into Practices of Digital Ethics: Five Risks of Being Unethical. Philos. Technol. 2019.

[102] For example, as was done with the AI Pact, which preceded the AI Act.

[103] Marchant GE, Governance of Emerging Technologies as a Wicked Problem, Vanderbilt Law Review, 2020.

[104] Steindl E, Safeguarding privacy and efficacy in e-mental health: policy options in the EU and Australia, International Data Privacy Law, 2023.

[105] The Risks and Challenges of Neurotechnology for Human Rights, UNESCO, 2023.

[106] Maia de Oliveira Wood G, The protection of mental privacy in the area of neuroscience: Societal, legal and ethical challenges. Scientific Foresight Unit, European Parliamentary Research Service, 2024.

[107] Ibid.

[108] From Vision to Reality: Promises and Risks of Brain-Computer Interfaces. Analysis and Research Team, Council of the European Union, 2024.

global community[109,110] ensuring that ethical standards are maintained as neurotechnologies evolve, and that safeguards to respect fundamental rights are in place. This aligns with the European Council's Strategic Agenda 2024-2029, which emphasizes competitiveness while ensuring inclusivity and social cohesion, and resonates with the 2024 Political Guidelines of President von der Leyen.

While there is an increasing body of soft law from related organisations, **no single piece of EU law directly governs neurotechnology**. Instead, several different policies apply to neurotechnology in a variety of contexts, mostly indirectly. Indeed, the EU's approach to technology governance emphasizes technology neutrality as a fundamental principle within its regulatory frameworks.[111] This technology-neutral approach ensures that no individual technologies are favoured or discriminated against; instead, the focus of regulation is to manage risks and address broader social impacts of technologies.

Case Study: NeuroSharp Headset

NeuroSharp Headset

A neurofeedback headset
to improve concentration

The future of productivity in education and the workplace. Designed with precision neurofeedback technology, the NeuroSharp Headset is an essential tool for anyone looking to enhance their cognitive performance and concentration. Whether you're a student aiming to boost your study efficiency or a professional seeking to maximize workplace productivity, this headset monitors your brain activity in real time, providing instant feedback to help refine your focus.

With customizable settings tailored to individual needs and a sleek, comfortable design, the NeuroSharp Headset is your partner in achieving unparalleled mental clarity and attention mastery. Embrace the power of advanced neurotechnology and transform how you learn and work.

Figure 2: The NeuroSharp Headset

To explore how current EU laws could apply to future neurotechnologies, we present a case study of a fictional, yet plausible company inspired by existing consumer neurotechnology: "NeuroSharp."[112] This case study begins by examining how previously discussed tensions manifest in this specific neurotechnology, followed by an analysis of EU governance challenges, including limitations in legal definitions, the regulation of rapidly evolving technologies, and the need to shift from addressing physical to mental harm. The reader is then invited to explore potential uses in both the wellness and medical spaces culminating in a focus on an extended application of the wearable consumer device.

[109] O'Sullivan S, et al., Neurotechnologies and Human Rights Framework: Do We Need New Rights? Council of Europe, n.d.

[110] International Bioethics Committee, Ethical issues of neurotechnology: report, UNESCO, 2021.

[111] The concept of "technology neutrality" was first introduced in 2002, and has since been reinforced in several regulatory instances, such as the 2009 revised telecommunications regulation, in 2011 with the internet policy Parliamentary resolution, and again with the GDPR. Since this approach calls for regulating based on the effects of a technology, rather than the hype or hyperbole associated with it, it should help manage the tension between evidence and hype.

[112] We developed a series of such scenarios for our workshops, based on both current and potential neurotechnologies. This is described in more detail in Section IV.2.

The NeuroSharp Headset is similar to other brain-sensing devices that are wearable, portable, user friendly,[113] and in some cases already in use by consumers.[114] NeuroSharp uses AI-mediated analyses of brain data to offer insights related to arousal, attention, mood, and stress amongst other brain states to help users optimize their wellness. It leverages neurofeedback, wherein the device provides feedback on mental states through visual, auditory, or haptic means.[115] This allows users to voluntarily influence their brain activity to achieve increased focus, relaxation, or emotional regulation.

Grey areas of NeuroSharp

Devices like NeuroSharp bring forward many of the ethical challenges raised earlier (i.e. transparency, privacy, data protection, consent, etc.). Accordingly, the development of these neurotechnologies has rightfully sparked debates about whether existing legal and governance frameworks are sufficient to address the concerns they raise. However, as previously noted, **focusing solely on legislative solutions to specific concerns risks overlooking conceptual grey areas surrounding neurotechnologies that impact both the ethical and governance conversations**. Next we describe and illustrate these grey areas in the NeuroSharp Headset.

NeuroSharp as an evolving technology: from consumer to medical

NeuroSharp is a multi-purpose device that could be used in many different ways.

What if...

1. NeuroSharp is deployed first as a personal wellness device?
2. NeuroSharp then transitions to a workplace tool for employers to monitor employees?
3. NeuroSharp realizes the data it collects can now be used to derive medical insights?
4. NeuroSharp advances to a new version, “NeuroSharp Plus” which also offers abilities to not only record, but also stimulate brain activity?

For each of these scenarios, we explore how existing legal frameworks - such as the GDPR, AI Act, MDR, etc. - could apply to NeuroSharp as it evolves.

[113] Mathews D, et al., Neurotechnology and Noninvasive Neuromodulation: Case Study for Understanding and Anticipating Emerging Science and Technology, NAM Perspect, 2023.

[114] Farahany N. The Battle for Your Brain. St Martin’s Publishing Group, 2023.

[115] Sitaram R, Ros T, Stoeckel L, et al., Closed-loop brain training: the science of neurofeedback. Nat Rev Neurosci 18, 2017.

Figure 3: Conceptual grey areas present in NeuroSharp

GREY AREA	DESCRIPTION
Evidence and Hype	The promotional language surrounding the NeuroSharp Headset reflects the potential benefits of the device. Considering the allure of neuroscience, publics may be more susceptible to unrealistic expectations regarding its capabilities. Also, the threshold for rigorous testing is lower for consumer products like NeuroSharp than the legal requirements for devices intended for medical purposes.
Empowerment and Vulnerability	The use of NeuroSharp in the workplace has the potential to enhance employees abilities while also exposing them to privacy and autonomy related vulnerabilities and potential coercion, particularly if their employer or insurance providers have access to such information.
Medical and Non-medical	Users, developers, and third parties might use NeuroSharp's initially collected non-medical data for analyses that lead to clinically relevant insights. This potential use complicates regulatory jurisdictions as well as consent processes.
Invasive and Non-invasive	Non-Invasive devices like NeuroSharp are often perceived as posing fewer risks than invasive technologies as they do not require surgical intervention. However, scientifically and ethically, this risk analysis may need to be evaluated as non-invasive technologies can also have impacts on the structure and function of the brain.

01. NeuroSharp enters the market as a personal wellness device.

NARRATIVE

NeuroSharp, like many of today's direct-to-consumer brain-sensing headsets, makes bold statements about its capabilities ("unparalleled mental clarity and attention mastery"). The public has historically been particularly compelled by gadgets that reference neuroscience, which has even generated an area of study dedicated to "neurohype."[116]

While the science is evolving with some promising findings, how reliably these technologies can deliver such cognitive enhancements remains unclear.[117] There are currently no technical standards for consumer neurotechnologies, nor are consumer neurotechnologies subject to the more rigorous safety and efficacy testing required of medical devices.

Regardless of whether NeuroSharp can fulfill its promises, NeuroSharp relies on data collection and analysis to provide a more personalised user experience. Under the GDPR, organisations are required to protect personal data, which is defined as any information relating to an identified or identifiable natural person ('data subject'), "by reference to [...] factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person."[118] NeuroSharp argues that they de-identify and anonymize all the data they collect and analyze them in aggregate. Therefore, under GDPR, they would not be designated as personal data, thus not requiring NeuroSharp to adhere to additional protections (such as limitations on collection, processing and sale of data to third parties).

ANALYSIS

There is an active debate on the adequacy and ambiguities of the GDPR's definition of personal data. The extent to which user data, particularly brain data, can be used to re-identify an individual will continue to evolve as more data is amassed, combined with other types of data, and analysis becomes faster and more complicated with AI.[119,120]

Re-identification can also become an important topic given the potential for discrimination. For example, analyses of brain data can lead to 'inferences' about a person's sexual or political preferences and behavioral patterns. This potential has led groups like UNESCO's International Bioethics Committee and the UK's Information Commissioner's Office to call for all brain data to be classified as sensitive data. The GDPR's primary focus on the input stage, when data is collected, may require further consideration of issues related to data processing and inferential analytics.

The above highlights the hype surrounding NeuroSharp's capacities and the complexity of the potential insights derived from data collected. These reflections underscore that these tensions should not be addressed by policy makers or experts alone, rather it points to the need for additional community involvement including developers, consumers and those from whom data is collected who are usually absent from these discussions. This type of involvement could enable a co-creation of policies that are more responsive to the real-world experiences, aspirations, and anxieties of those who may be most affected by these technologies.

116 Lilienfeld, SO et al., Neurohype: A field guide to exaggerated brain-based claims. In: The Routledge handbook of neuroethics, Routledge/Taylor & Francis Group. 2018.

117 Neurotech Evidence Book, Internet of Brains, 2023.

118 Article 4, GDPR.

119 Klonovs CK, et al., "ID Proof on the Go: Development of a Mobile EEG-Based Biometric Authentication System," in IEEE Vehicular Technology Magazine, 2013.

120 Jwa AS, Koyejo O, Poldrack RA, Demystifying the likelihood of reidentification in neuroimaging data: A technical and regulatory analysis, Imaging Neuroscience, 2024.

02. NeuroSharp becomes a workplace technology.

NARRATIVE

Workplace wearables have already been used to track fatigue for dangerous jobs such as long-haul truck drivers and miners, on the grounds that these devices can save lives and costs lost to catastrophic accidents.

NeuroSharp contracts with corporations to deploy their device in offices, allowing employees and their employers to monitor and track employees' stress, mood, and attention levels.[121] Proponents argue that these devices can boost employees' productivity, wellness, and general health and happiness. They also allow their employers to better manage their team's resources, keeping stress at bay by monitoring for signs of burnout. In some cases, employers use the insights from these devices to make decisions about holiday allocations and pay raises.

ANALYSIS

Deploying NeuroSharp as a workplace technology blurs the line between empowering employees and exposing their vulnerabilities to unwanted surveillance. Critics worry about potential brain exploitation due to the inherent power dynamics of the workplace, as well as risks to discrimination and overall implications for employee autonomy and rights.[122,123]

Employees have some legal assurances of privacy rights[124] The GDPR requires that employers obtain consent to process personal data, and such processing is permissible only when necessary for performing a contract or advancing the "legitimate interests" of the business. However, while employers can have discretion in interpreting what constitutes a "legitimate" business interest, ultimately consent for processing personal data must benefit the employee to be lawful. In the case of sensitive data, employers would need both an exemption and a legal basis. In situations where significant power imbalances exist (such as an employer-employee relationship), consent alone may be insufficient to ensure human dignity, autonomy, and agency. This underscores how in certain contexts, some legal instruments may fall short in addressing ethical issues and ensuring human rights.

In the EU, the European Convention of Human Rights and the European Court of Human Rights would play a key role in adjudicating the legitimacy of an employer's justification for deploying neurotechnologies like NeuroSharp for workplace surveillance. If brought to court, it is unlikely that these types of use would be deemed justifiable in the workplace, particularly considering the power imbalances between employers and employees. These imbalances would make it difficult for employees to legitimately consent to workplace neurosurveillance.

Additionally, as devices like NeuroSharp use AI, the AI Act would apply, requiring specific attention to transparency and consent when it comes to emotion-recognition systems and biometric data (NeuroSharp claims gain insights from data on mood and mental arousal, for example).

[121] Ackerman E, Strickland E, Are you ready for workplace monitoring? IEEE, 2022.

[122] Muhl E, Andorno R, Neurosurveillance in the workplace: do employers have the right to monitor employees' minds? Frontiers in Human Dynamics, 2023.

[123] Farahany N. The Battle for Your Brain. St Martin's Publishing Group, 2023.

[124] Can my employer require me to give my consent to use my personal data? Rights for citizens, European Commission.

Since the Act has been only recently passed we still do not know how data derived from a device like NeuroSharp would be categorised. Article 5(1)(f) in the AI Act bans the use of AI system to identify or interfere with employees emotions[125] in the workplace except for medical and safety reasons and excludes physical states, such as fatigue. The issue with NeuroSharp is that it is designing devices for concentration and focus and it is not clear whether they are to be understood categorially as emotional, physical, or both. If this is true, this would place NeuroSharp in a regulatory grey zone.

The AI Act also mandates that workers and their representatives be informed whenever AI systems are deployed. The European Trade Union Confederation (ETUC) has pushed for a directive on algorithmic systems in the workplace that would require human oversight of AI in the workplace and empower trade unions in the development of AI systems.

This highlights the need for ongoing communication and coordination in the governance of neurotechnology in the workplace. Understanding where to draw the line between unwanted surveillance and promotion of tools that can empower employees is key. Engaging diverse communities, including labor unions and technology users early in the policymaking process can provide greater insights on how to use and regulate these technologies as they become more widely deployed.

03. NeuroSharp has become so advanced it can derive medical insights from the data it collects.

NARRATIVE

Since its release, NeuroSharp has gathered vast amounts of neural data and collaborated with the medical research community. It has advanced its algorithmic processing to the point that it can now be used to glean medical insights on mental health status and mental disorders (such as diagnosing depression, burnout, PTSD, ADHD, autism, etc.), and can even be used to predict trajectories of brain health by detecting early signs of neurodegeneration.

NeuroSharp realises it has the potential to democratise access to brain health diagnostic tools, making them more affordable and accessible to individuals who would otherwise face financial or other obstacles. By making earlier detection possible, it will empower people to seek out treatment at earlier stages of mental disorder and offer the potential for more personalised - and thus effective - treatment.

ANALYSIS

This repurposing of the data NeuroSharp has collected illustrates the porousness between medical and non-medical applications and the challenges of existing jurisdiction-specific tools. In the case of NeuroSharp, the data was not collected using health data protocols, which would involve offering additional safeguards for data management as well as consenting for analyses that could lead to re-identification of individual patients. For NeuroSharp to comply with the GDPR, it needs to meet specific requirements.

One requirement is related to how the data is processed. As stated earlier, some organisations have argued that data derived from neurotechnology could run the risk of re-identification and thus could qualify as personal data. If NeuroSharp's data is classed as personal data, processing these data for secondary use is permissible according to the GDPR if done in a manner that ensures appropriate security. Measures include protection against unauthorised or unlawful processing as well as accidental loss, destruction or damage, by using

[125] Recital 18, AI Act.

[126] Paek AY, Brantley JA, Evans BJ, Contreras-Vidal JL. Concerns in the Blurred Divisions between Medical and Consumer Neurotechnology. IEEE Syst J. 2021.

appropriate technical or organisational measures to maintain data's 'integrity and confidentiality.'

Another requirement is related to the purpose for which the data is processed. NeuroSharp argues that it plans to process the data for scientific research, and the GDPR allows for secondary use of data in this way. The GDPR defines scientific research broadly, as the "technological development and demonstration, fundamental research, applied research and privately funded research" conducted by both public and private entities (Recital 159). That research should be "in the public interest in the area of public health." Therefore, under the GDPR, NeuroSharp could repurpose these data for medical insights under the umbrella of scientific research.

The definition of scientific research is located in the GDPR recitals, which while not legally binding, are likely to influence the courts in their application of the law. A complicating factor is that Member States often define research differently, with countries such as Germany and Finland offering no formal legal definition.[127] Additionally, the variability across legal regimes makes it possible for companies to forum-shop for domestic legal interpretations. Similarly, the notion of "public interest" is fraught with ambiguity. This suggests that setting priority areas for public health would benefit from a dialogue with a broader group of community stakeholders both at the regional and national level.

Finally, in light of the upcoming implementation of the European Health Data Space, NeuroSharp would additionally need to consider and explore whether its data collection protocols would fit interoperability criteria with Electronic Health Records, and whether it would choose to participate in this framework. NeuroSharp would need to decide whether the costs and resources needed for complying with these requirements would result in sufficient business returns from consumers who would want this feature.

04. NeuroSharp launches NeuroSharp Plus, a 'non-invasive' sensing and stimulating device.

NARRATIVE

NeuroSharp feels that keeping its classification as a wellness device will help avoid the expensive regulatory compliance measures required for medical devices - for now. NeuroSharp also believes their insights on mood, stress, and wellness could offer indications for treatment avenues for those with diagnosed medical conditions like mood disorders, even if it is not technically a medical device.

So instead, Neurosharp is excited to offer an extended function of its headset, NeuroSharp Plus. NeuroSharp Plus not only offers brain sensing capacities, but also brain stimulation through trans-cranial electrical currents. The stimulation is claimed to help increase mood and attention.

ANALYSIS

Medical devices typically undergo additional safety scrutiny under the Medical Device Regulation (MDR). However, wearable, "non-invasive", external brain sensing and stimulating devices that are marketed to consumers have historically not undergone the level of scrutiny required for medical devices. The reason for less scrutiny is that non-invasive brain stimulation devices are often viewed as less risky to consumers. However, **external stimulation of the brain does not necessarily mean it is 'non-invasive' to brain**

[127] Meszaros J, Compagnucci MC, Minssen T, The Interaction of the Medical Device Regulation and the GDPR: Do European Rules on Privacy and Scientific Research Impair the Safety and Performance of AI Medical Devices? In: The Future of Medical Device Regulation: Innovation and Protection. Cambridge University Press, 2022.

structure or function. This case forces us to confront conceptual concerns regarding the safety distinction between invasive and non-invasive devices.

Since NeuroSharp Plus is not classified as a medical device, it would in theory avoid this scrutiny. However, to address this gap, the EU has introduced several new updates to the MDR, and potentially to the forthcoming General Product Safety Regulation (GPSR)[128]

First, the MDR expanded its scope to address non-medical stimulation devices: Annex XVI focuses on specific technical aspects independent of the intended purpose. Article 1(2) in coordination with Annex XVI incorporates a list of non-medical products' technical functions within the medical device framework. The Article includes equipment that "apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify activity in the brain." Therefore, any neurotechnology that has a stimulating capacity, like NeuroSharp Plus, is now subject to the MDR, and any neurotechnology that is subject to Annex XVI undergoes an MDR risk classification. NeuroSharp therefore has to comply after all.

Second, the MDR reclassifies **non-medical brain stimulation devices as high risk III**, imposing stricter requirements than even some medical devices, moving them from the lowest risk classification to the highest.[129,130,131] Class III devices are subject to the highest level of scrutiny including a rigorous pre-market investigation with rigorous levels of safety and performance data and post-market surveillance.

An additional new regulation that is not domain-specific to neurotechnology, the GPSR offers a horizontal mechanism to protect consumer safety concerns related to neurotechnologies. The GPSR will be effective as of December 2024, and it will bring forth provisions that can be applied to general safety assessments for consumer devices like NeuroSharp. Some of these assessment criteria will include the evaluation of the potential to be used beyond the intended use (e.g. wellness) in ways that might be considered misuse (e.g. medical applications).[132]

While these updated regulations are meant to protect consumers, they have sparked concerns among researchers. Some claim the MDR's reclassification of non-invasive brain stimulation to Class III risk is too strict and scientifically unjustified.[133] Researchers using non-invasive brain stimulation devices fear that the new classification will harm potential advancements and reduce access to the benefits of non-invasive brain stimulation for the public.[134]

Furthermore, some complain that the public consultation process did not involve experts in the field and noted that it received limited feedback from the public. This indicates the need for broader engagement efforts, including researchers and developers when revising or crafting new regulation to foster greater trust and ensure the societal benefits of these technologies can be realised.

[128] Steindl E, Consumer neuro devices within EU product safety law: Are we prepared for big tech ante portas? Computer Law & Security Review, 2024.

[129] Bikson M, et al., Limited output transcranial electrical stimulation 2023 (LOTES-2023): Updates on engineering principles, regulatory statutes, and industry standards for wellness, over-the-counter, or prescription devices with low risk. Brain Stimul., 2023.

[130] Guidance on classification of medical devices, Medical Device Coordination Group Document, 2021.

[131] Bublitz JC, Unforeseen side-effects of the novel regulation of non-medical brain stimulation devices in the European Union, Brain Stimul. 2023.

[132] Steindl E, Consumer neuro devices within EU product safety law: Are we prepared for big tech ante portas? Computer Law & Security Review, 2024.

[133] Baeken C, et al., European reclassification of non-invasive brain stimulation as class III medical devices: A call to action. Brain Stimul. 2023

[134] Antal A, et al., The consequences of the new European reclassification of non-invasive brain stimulation devices and the medical device regulations pose an existential threat to research and treatment: An invited opinion paper, Clin Neurophysiol., 2024.

This discussion was not meant to provide a complete legal analysis but rather to illustrate some challenges in governing neurotechnologies even in regions with robust and comprehensive hard laws. The narrative above demonstrates that the EU is equipped with regulation that readily applies to neurotechnology. However, challenges remain to practically implement these regulatory tools due to conceptual grey areas and lack of definitional consensus attendant to the applications of neurotechnology.

Challenges remain to practically implement these regulatory tools due to conceptual grey areas and lack of definitional consensus attendant to the applications of neurotechnology.

As illustrated above, the challenges of deciphering good evidence in an ecosystem of hype; potential for empowerment and exploitation of vulnerabilities; the porousness between medical and nonmedical insights as well as the muddiness of distinctions between invasive and non-invasive warrant more robust dialogues on how to effectively apply, and even create, better-tailored regulatory mechanisms that guarantee respect for fundamental rights, while enabling safe innovation. Furthermore, these conceptual ambiguities will warrant harmonisation of terminology and language across neurotechnology governance efforts (Recommendation 3).

Towards ethical governance of neurotechnology

We propose addressing the ethical governance challenges of neurotechnology by promoting inclusive **anticipatory governance with multi-stakeholder participation**, as well as paying careful attention to **conceptual framing and clarity**.

Anticipatory governance and multi-stakeholder participation go hand in hand

An anticipatory approach is essential due to the potentially profound, rapid, and disruptive impact of neurotechnology on individuals, societies, and even fundamental concepts of human identity.[135] By proactively addressing future developments and their implications, policymakers can mitigate risks, ethical concerns, and societal challenges before they materialise. This enables the creation of flexible, adaptive policies that keep pace with technological advances, helping to counter the "pacing problem"[136] and reducing the need for reactive regulation later.

Key to effective anticipatory governance is strategic foresight, a discipline used by organisations and governments that promotes long-term thinking and scenario planning to anticipate future trends, challenges, and opportunities. By systematically exploring multiple possible futures, strategic foresight allows policymakers to develop strategies that are robust under different conditions, ensuring preparedness for a range of potential outcomes and the best societal outcomes possible.

At the 2024 OECD Science and Technology Policy Ministerial meeting, where the OECD Neurotechnology Toolkit was launched, the panel "Human enhancement: emerging technology and the human future" brought together experts to discuss the societal and ethical implications of technology that directly interface with the brain. Within the broader discussion of risks to human rights, techno-solutionism, and inequality, one speaker simply stated that if neurotechnology is to benefit everyone, "**we must first ask people what they actually want**."

[135] Rainey S, An Anticipatory Approach to Ethico-Legal Implications of Future Neurotechnology. Sci Eng Ethics 30, 2024.

[136] Marchant G, Addressing the Pacing Problem, In: The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight, The International Library of Ethics, Law and Technology. 2011.

In this vein, central to anticipatory governance of emerging technologies is the active engagement and participation of diverse stakeholders in an inclusive and collaborative way[137] — including researchers, innovators, developers, scientists, industry leaders, ethicists, patients, clinical practitioners, and the general public (see Annex for a full list of key stakeholders relevant to neurotechnology). This is essential to ensure that diverse perspectives, hopes, and concerns are integrated into policy processes, and creates opportunities to explore how societal values influence the direction of research and innovation, the development and adoption of technologies, and their impact on human relationships. Furthermore, engaging a broad diversity of stakeholders is crucial to proactively identifying potential risks, ethical concerns, and societal impacts that may not be immediately visible to policymakers, rather than scrambling to react to controversies after they arise. Thus, inclusivity enables a more anticipatory and responsive form of governance, which is particularly vital in the rapidly evolving field of neurotechnology.

Early and equitable public engagement can facilitate the co-creation of technology policies that are not only widely beneficial but also more readily accepted by society.

Involving diverse perspectives in policy decisionmaking fosters public trust in both the governance processes and the market's development by ensuring that diverse voices are heard and reflected along the way. This approach demonstrates a commitment to inclusive decision-making that reflects the varied values and concerns of stakeholders, aiming at more effective policies that are ethically sound and socially desirable. Early and equitable public engagement can facilitate the co-creation of technology policies that are not only widely beneficial but also more readily accepted by society. This aligns with recent EU research on knowledge valorisation, which underscores the critical role of involving the public early and equitably in technology development.[138]

A stakeholder map relevant to the neurotechnology debate, along with criteria for ensuring diversity of all kinds in stakeholder engagement efforts, is provided in the Annex.

In particular, while the relevance of including those with lived experience in policy and programming has been recognised by public health organisations,[139] lived experience advocates largely remain underrepresented in current conversations in neurotechnology governance. Another recognised underrepresented voice in neurotechnology governance is that of developers of the technology either in the public or private sector ecosystem.[140] The recent UNESCO neurotechnology landscaping report suggests that private sector investment is clearly exceeding public investments.[141] Any proposed neurotechnology governance will struggle to be implemented without input from the private sector.[142]

[137] Framework for Anticipatory Governance of Emerging Technologies, OECD Science, Technology and Industry Policy Papers, OECD Publishing, 2024.

[138] Pottaki I, et al., Fostering knowledge valorisation through citizen engagement, European Commission, Directorate-General for Research and Innovation, 2024.

[139] WHO framework for meaningful engagement of people living with noncommunicable diseases, and mental health and neurological conditions, WHO, 2023.

[140] Garden H, et al, "Responsible innovation in neurotechnology enterprises", OECD Science, Technology and Industry Working Papers, No. 2019/05, OECD Publishing, 2019.

[141] Hain, DS, et al, Unveiling the neurotechnology landscape: Scientific advancements, innovations and major trends, UNESCO, 2023.

[142] Pfotenhauer SM, et al., Mobilizing the private sector for responsible innovation in neurotechnology. Nat Biotechnol, 2021.

Implementing anticipatory and participatory approaches for neurotechnology governance

There is a wealth of mechanisms and methodologies designed for engaging stakeholders and unpacking the complex societal issues and tensions associated with emerging technologies, especially for policy and governance purposes. Public engagement throughout the lifecycle of neurotechnology — spanning laboratory research, technology development, industry operations, policy-making, compliance, and oversight — can take various forms.[143] Different engagement formats and forums yield different outcomes, each suited to specific points in the policy-making process. Informational formats, such as events, public debates, newsletters and blogs, are effective for raising awareness and gathering input from the broader public. In contrast, more collaborative formats, such as focus groups, interactive workshops, multi-stakeholder foresight exercises, citizen deliberations forums, and shared decision-making platforms, provide deeper, more structured opportunities for stakeholders to co-create policies and contribute to regulatory discussions.

Such participatory methods not only play a role in the initial development of policies but are also vital once governance frameworks are in place. Public engagement can be used to monitor policy compliance, stress-test legal frameworks, and guide necessary reforms as neurotechnologies — and their applications — evolve. Figure 4 illustrates the many layers and types of interactions with the public from unidirectional information transfer (represented on the left in grey) to more multi-directional exchanges and dialogue (moving toward the right in dark blue). These activities are shaped by multiple dimensions of interactions between experts and public audiences-the goal of the interaction; the specific topic or focus; the attitudes, behaviors, and expectations of public.

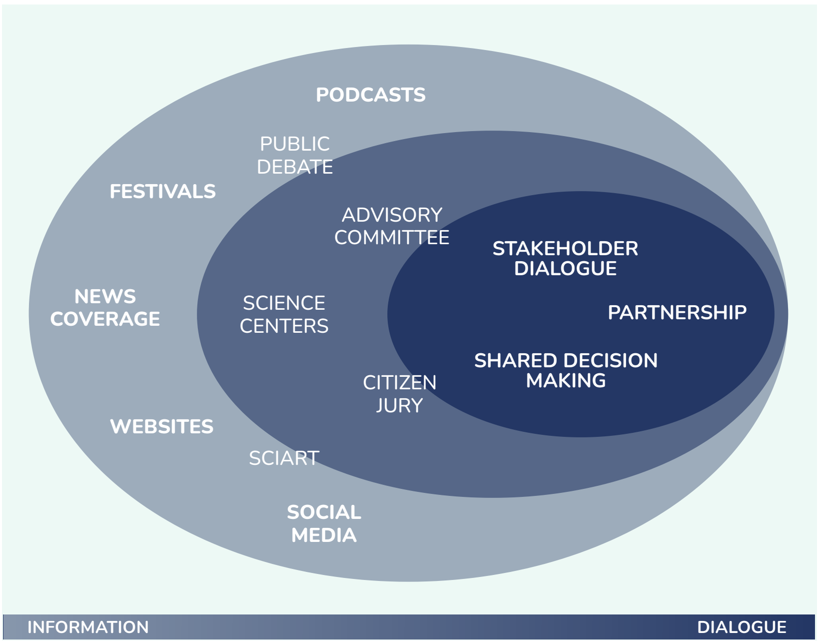


Figure 4: Public Communication Spectrum. Reproduced with permission from Das et al, 2022[144]

We posit that the most productive approach to addressing the issues and tensions described in previous sections is inclusive participatory engagement, particularly on the "dialogue" end of the spectrum (highlighted in the darkest colour in Figure 4), characterised by partnership and co-creation. (Recommendation 2).

[143] Bitsch L, Rekve K, Neuhaus SV, et al., The landscape of Science, Ethics & Public engagement and its Potential for the Future, Danish Board of Technology Foundation, 2021.

[144] Das J, et al., Neuroscience is Ready for Neuroethics Engagement, Frontiers in Communication, 2022.

Inclusive engagement processes must promote equal footing among all participants, as both the public and experts bring valuable expertise, and perspectives.

Both patients and scientists have pushed for models beyond reliance on unidirectional consultations and surveys in neurotechnology governance, advocating for upgraded models of co-creation spaces for dialogue.[145,146] Importantly, inclusive engagement processes must promote equal footing among all participants, as both the public and experts bring valuable expertise, and perspectives[147] Dialogue fosters much richer public engagement, and can reveal connections between issues that are otherwise not apparent from the perspective of an expert. Examples of such previous and ongoing dialogue efforts include the Human Brain Project's 2021 citizen consultation project on the ethics of dual use of neurotechnologies[148] as well as the recently launched Implanted Brain Computer Interface Collaborative Community (iBCI-CC).

Particularly relevant to neurotechnology is a recent framework proposed for neuroethics engagement.[149] This framework fosters deeper reflection and mutual learning by addressing the complex issues raised by neuroscience and neurotechnology. It highlights six key attributes needed for truly inclusive and collaborative engagement, wherein diverse voices are not only heard but also incorporated into decision-making processes: humility, openness, reflexivity, intellectual agility, creativity, and cultural curiosity (see Annex for full description).

Some neuroethics engagement methods that can be deployed are described below, summarised in the Annex, and explained in greater detail by the (U.S) National Informal STEM Education (NISE) Network.

One such method uses neurotechnology futures scenarios, which we used in our workshop. An extract is shown with the case study on NeuroSharp in Section III.4. We developed a series of scenarios, based on both current and potential neurotechnologies, inspired by the NISE Network's Neuro Future Card Game. These scenarios were paired with a set of "provocation cards" that posed challenging questions about the ethical dimensions and societal implications of these fictional technologies. Participants were then presented with a menu of governance options and invited to weigh the pros and cons of each, considering the particular combination of technology scenarios and provocations that they encountered. Using these types of tools can facilitate deeper engagement and help anticipate and address potential ethical, legal, and policy challenges beyond safety and regulatory compliance.

Another example of a specialised engagement activity are hackathons. The IoNx hosted its inaugural neuroethics hackathon at the FENS Forum 2024 in Vienna.[150]

[145] Antal A, et al., The consequences of the new European reclassification of non-invasive brain stimulation devices and the medical device regulations pose an existential threat to research and treatment: An invited opinion paper, Clin Neurophysiol., 2024.

[146] Zaratin P, Bertorello D, Guglielmino R, et al., The MULTI-ACT model: the path forward for participatory and anticipatory governance in health research and care. Health Res Policy Sys, 2022.

[147] Bell L, et al., Public engagement with science: A guide to creating conversations among publics and scientists for mutual learning and societal decision-making. Boston, MA: Museum of Science for the NISE Network, 2017.

[148] Aicardi C, Opinion on 'Responsible Dual Use' Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology, Human Brain Project, 2021.

[149] Das J, et al., Neuroscience is Ready for Neuroethics Engagement, Frontiers in Communication, 2022.

[150] Rommelfanger K, et al., Neuroethics Hackathons Bridge Theory to Practice, [Pre-Print] 2024.

In this case, each team was presented with one of three scenarios, similar to the ones mentioned earlier. The groups took on the identity of an AI-enabled neurotech company and were tasked with presenting a testimony at a government hearing to convince policymakers that they were creating an ethically viable product. This activity encouraged participants to identify, reflect, and jointly address the ethical dimension of neurotech design, development, and deployment.

These engagement activities have successfully encouraged participants to reflect on their own values, consider other perspectives, and critically assess the societal implications of scientific discoveries and new technologies—ultimately supporting learning and exchange among diverse community members with different perspectives and roles (see Annex). With some tailoring, these methods for inclusive neuroethics engagement can be readily applied in an EU policy context, via a number of different channels - as we will explore in the next section.

The EU's toolbox of participatory policy-making

Over the past two decades, the EU has increasingly prioritised policymaking that incorporates citizen involvement,[151] particularly for technology policy.[152] Since 2015 the European Commission has rolled out a stakeholder-centered approach through its Better Regulation Agenda, designed to to involve citizens, businesses, and stakeholders in the decision-making process. The goal is to ensure that its policy is evidence-based, high-quality, inclusive, and legitimate.

The centerpiece of the Better Regulation agenda is the "Have Your Say" platform, which allows citizens and stakeholders to provide feedback on legislative proposals. Complementing this, the Conference on the Future of Europe has given rise to the European Citizens Panels, a new initiative bringing together randomly selected EU citizens to discuss key upcoming proposals, making them a key tool of agenda setting. Furthermore, in 2023, the Commission issued a Recommendation on promoting the engagement and effective participation of citizens and civil society organisations in public policy-making processes.

Since 2021, the EU's Better Regulation agenda (and corresponding policymaking toolbox) has set out to ensure that policymaking is fit for the future and resilient by including the possibility of using strategic foresight in impact assessments. With this important initiative, the EU has laid groundwork for stakeholder engagement to seed more effective, anticipatory governance, particularly for emerging technologies such as neurotechnology. Strategic foresight strongly promotes stakeholder engagement and inclusive dialogue as pillars for anticipating future challenges and opportunities, particularly those brought about by new technologies. Rather than predicting the future, it leverages insights about potential futures to design more resilient and adaptable policies.

The Joint Research Centre plays a key role in generating knowledge to inform policy, and supporting other Directorates-General in their policy-making efforts

[151] Participate, interact and vote in the European Union, European Commission.

[152] Frahm N, Doezema T, Pfotenhauer S, Fixing Technology with Society: The Coproduction of Democratic Deficits and Responsible Innovation at the OECD and the European Commission. Science, Technology, & Human Values, 2022.

One important initiative is the annual Science for Policy foresight exercise, which involves broad, inclusive, and participatory stakeholder engagement through a series of workshops, focusing on a different theme each year.

through its Competence Centres on foresight and participatory and deliberative democracy. One important initiative is the annual Science for Policy foresight exercise, which involves broad, inclusive, and participatory stakeholder engagement through a series of workshops, focusing on a different theme each year, with 2023 devoted to the theme of fairness and sustainability.[153]

The European Parliament has also integrated foresight into its working methods,[154] particularly through its Scientific Foresight Unit - which administers the Panel for the Future on Science and Technology - and regularly conducts stakeholder engagement.[155] A notable recent example is a study on the societal implications of gene editing that involved a series of surveys and workshops to explore policy options for regulation.[156]

The EU is known for tailoring stakeholder engagement to align with the specific needs of the policy issue it is addressing. A good example of this is the development of the 2022 European strategy for a Better Internet for Kids: in preparing this strategy, the Commission organised around 70 consultations with over 750 children, to embed their views on online risks, such as harmful content, cyberbullying or disinformation, and opportunities into the strategy that affected them.

The examples above largely reflect a "top-down", government-led approach. This model can benefit from complementary "bottom-up" citizen-led approaches including grassroots movements and community-driven efforts. Notably, the European Citizens' Initiatives allows citizens to call on the Commission to propose new legislation. Citizens can also submit petitions to the European Parliament "to conduct an ongoing reality check on the way in which European legislation is implemented." Furthermore, EU Member States such as Ireland and Estonia also engage with their citizens in the policymaking process. For instance, Ireland regularly uses Citizens' Assemblies with randomly selected citizens to deliberate on complex issues such as biodiversity.[157] Estonia uses its e-Governance platform to enable citizens to propose legislation and participate in online consultations.[158] At the local level, cities such as Brussels, Milan, and Paris are also institutionalising deliberative forums in the form of permanent climate assemblies.[159,160,161]

The EU also enables bottom-up stakeholder engagement activities. For example, the Engage2020 Action Catalogue is a project funded by the European Commission, which developed a toolkit consisting of 57 different methods with the common denominator that their focus is research driven by involvement and inclusion.

[153] Towards a fair and sustainable Europe 2050: Social and economic choices in sustainability transitions, Joint Research Centre, European Commission, 2023.

[154] Van Woensel L, Guidelines for foresight-based policy analysis. European Parliamentary Research Service, 2021.

[155] Garcia Higuera A, A framework for foresight intelligence - Part 2: Online stakeholder engagement. European Parliamentary Research Service, 2021.

[156] Van Woensel L, Mahieu V, Pierer C, Regulating genome editing: Societal hopes and fears, Scientific Foresight Unit (STOA), European Parliamentary Research Service, 2021.

[157] https://citizensassembly.ie/

[158] The Five Factors of Success Behind Estonia's Citizen Empowering Platform, European Citizens´ Initiative Forum, 2023.

[159] Brussels launches world's first permanent Citizens' Assembly on Climate, g1000, 2024.

[160] Permanent Citizens Assembly on Climate, Milan Change Air.

[161] Paris Citizens' Assembly.

The European Commission funds bottom-up approaches in society through its research programs, such as MULTI-ACT, as part of its Horizon Europe research and innovation framework. MULTI-ACT integrates patient engagement with governance and impact assessment. This approach enables stakeholders to co-create with patients, recognizing their input as essential to advancing a shared mission. Such strategic decisions in public engagement programs can empower vulnerable groups and lived experience participants, in contrast to engagement efforts that only seek their feedback late in the decision-making for research, development, or policy.

These examples show that the EU has the mechanisms and tools needed to conduct the type of stakeholder engagement necessary to support an inclusive neurotechnology governance dialogue. **The challenge lies in the motivation and resources to implement these tools, as well as in effectively tailoring them to the specificities and ethical issues raised by neurotechnology**. A particular focus must be placed on fostering public engagement alongside expert involvement. In previous sections we provided analysis as well as suggested tools to deploy in support of these efforts (see Annex). In the final sections we will discuss these challenges in more detail and offer concrete recommendations on how to proceed.

Challenges to participatory policy-making

Despite efforts to make EU policies more transparent, evidence-based, and responsive to the needs of its citizens in general, inclusive practices are not always optimally integrated into governance processes[162] and, at times, they can be entirely absent.[163,164] The bottom line is that inclusive processes are difficult and require an alignment and commitment of human and financial resources.

A number of challenges have been noted, including lack of conceptual clarity (on both content and process), practical (lack of time, skills, and resources); legal (unclear legal integration and enforcement);[165] and institutional (evolving or ambiguous infrastructure for implementation).[166] Furthermore, unclear definition of the goals of engagement and the imbalance of decision-making power across communities, scientists, policymakers, and entrepreneurs hinders inclusive practices.[167] The matter of impact of these instruments (consultations, foresight exercises, etc.) has risen to prominence so much so that JRC is currently conducting a study to explore the impact of participatory process on policy-making, which indicates that strengthening participatory policy-making is rising on the agenda for the European institutions themselves.[168]

[162] Casale Mashiah D, et al., Responsible research and innovation in Europe: empirical evidence from regional planning initiatives in Austria, Norway, and Spain. European Planning Studies, 2023.

[163] Griesdoorn F, Kroesen M, Vermaas P, van de Poel I. The presence of Responsible Research and Innovation in the perspectives of Dutch policy officers regarding innovation with quantum technology, Journal of Responsible Technology, 2023.

[164] Anghel S, The use of strategic foresight in Commission impact assessments. Existing practices and the way forward, Policy Foresight Unit, European Parliamentary Research Service, 2024.

[165] Griessler E, et al., The Drama of Responsible Research and Innovation: The Ups and Downs of a Policy Concept. In: Putting Responsible Research and Innovation into Practice. Library of Ethics and Applied Philosophy, 2023

[166] Anghel S, The use of strategic foresight in Commission impact assessments. Existing practices and the way forward, Policy Foresight Unit, European Parliamentary Research Service, 2024.

[167] Bitsch L, Rekve K, Neuhaus SV, et al., The landscape of Science, Ethics & Public engagement and its Potential for the Future, Danish Board of Technology Foundation, 2021.

[168] Dunlop T, Understanding the Impact of Citizen Engagement on Policy, Institutions & Society, Community of Practice of the Competence Centre on Participatory and Deliberative Democracy, 2024.

These dynamics indicate **the need to frame participatory processes as essential for ensuring that new policies are sound, inclusive, and future-proof**.

The limitations of top-down approaches highlight the needs for complementary bottom-up approaches that can enrich top-down methods and enhance inclusivity in neurotechnology governance strategies. However, bottom-up approaches also have limitations. While they can offer greater participation and can be led by diverse communities, one potential limitation is how the findings from these approaches can effectively get back to policy-makers.[169] Therefore, while bottom-up approaches can be a helpful complement to top-down approaches that may fall short and vice-versa.[170]

Regardless of which participatory approach is used, policy dialogues must not only include a diverse range of stakeholders (see Annex), but also **enable the findings from participatory events to be translated into policy implementation** (Recommendation 2.4). A critical part of this translatability will be related to how the issues are framed and concepts are described.

Framing, Conceptual Clarity, and Language

The way in which start-ups in the neurotechnology sector frame ethical issues has drawn attention, emphasizing the need for a broader discussion on framing within this context.[171,172,173] **The public and practitioners, including policymakers and public administrators, often overlook the influence that "framing" can have on facilitating public dialogue on emerging technologies**.[174] For example, framing a neurotechnology as a "breakthrough" or as a "disruptive technology" can set the stage for very different conversations, which can impact on the outcome of those conversations.

Notably, culture, the dynamic set of values, beliefs, assumptions, and worldviews found in diverse societies and regions, plays a key role in shaping frames: it influences which scientific outputs are prioritised, how they are viewed, how they are integrated into society, and which ethical issues resonate more strongly.[175,176]

Yet there has been comparatively less focus on the primary tool through which these frames are created and communicated: language. The choice of words and the concepts within a frame when discussing neurotechnologies can evoke specific emotions, associations, and interpretations.[177] For example, terms like 'brain chips,' 'mind-reading,' or 'neurorights' can generate emotional responses - references to the brain and "neuro-" prefixes can be persuasive.[178]

[169] Bauer A, Bogner A, Fuchs D, Rethinking societal engagement under the heading of Responsible Research and Innovation: (novel) requirements and challenges. Journal of Responsible Innovation, 2021.

[170] Frahm N, Doezema T, Pfotenhauer S, Fixing Technology with Society: The Coproduction of Democratic Deficits and Responsible Innovation at the OECD and the European Commission. Science, Technology, & Human Values, 2022.

[171] MacDuffie KE, Ransom S, Klein E, Neuroethics Inside and Out: A Comparative Survey of Neural Device Industry Representatives and the General Public on Ethical Issues and Principles in Neurotechnology, AJOB Neurosci, 2022.

[172] Knopf S, Frahm NM, Pfotenhauer S, How Neurotech Start-Ups Envision Ethical Futures: Demarcation, Deferral, Delegation. Sci Eng Ethics, 2023.

[173] Moss AU, Li ZR, Rommelfanger KS. Assessing the Perceived Value of Neuroethics Questions and Policy to Neuro-Entrepreneurs. Front Neurosci. 2021.

[174] McNealy JE, Framing and Language of Ethics: Technology, Persuasion, and Cultural Context, Journal of Social Computing, 2021.

[175] Ochang P, Eke D, Stahl BC, Towards an understanding of global brain data governance: ethical positions that underpin global brain data governance discourse. Front Big Data. 2023.

[176] Das J, et al., Neuroscience is Ready for Neuroethics Engagement, Frontiers in Communication, 2022.

[177] Salles A, Farisco M, Neuroethics and AI ethics: a proposal for collaboration, BMC Neurosci25, 2024.

[178] Lilienfeld, SO et al., Neurohype: A field guide to exaggerated brain-based claims. In: The Routledge handbook of neuroethics, Routledge/Taylor & Francis Group. 2018.

Responsible conceptualization entails being clear about the reality of the capacities and limits of neurotechnology development as opposed to overly idealistic or dystopian narratives of neuroscience, often promulgated through pop culture and science fiction.[179,180] **Given that concepts play a critical role in setting ethical priorities and shaping public attitudes towards science and innovation, ensuring conceptual clarity is essential for effective communication, narrative formation, and governance discussions.**[181,182,183,184]

The field of neurotechnology is rife with ambiguities. Consider the "grey area" between invasive and non-invasive devices. The terms used in the discussion are arguably conceptually problematic. Conceptually, because invasiveness tends to be viewed as purely physical, the concept obscures the potential for significant invasiveness through non-physical means. In doing so they oversimplify the ethical landscape and the normative discussion. To avoid the issues associated with labeling technologies as "invasive" or "non-invasive," it might be more effective to use the distinctions of "implantable" and "non-implantable." This approach circumvents unexamined assumptions about how to understand "invasive" and the idea that less invasive technologies are inherently less problematic.

This underscores the need to develop a common lexicon of terminology, co-created with a diverse group of stakeholders (see Annex), in order to mitigate framing biases and linguistic misunderstandings caused by complex and ambiguous neurotechnology terminology (Recommendation 3.1).

[179] Think for example of the Matrix, Inception, and Total Recall, and how they shape public perceptions of humans interfacing with computers.

[180] Salles A, Farisco M, Neuroethics and AI ethics: a proposal for collaboration, BMC Neurosci25, 2024.

[181] Farisco M, Salles A, Evers K, Neuroethics: A Conceptual Approach. Cambridge Quarterly of Healthcare Ethics. 2018.

[182] Salles A, Evers K, and Farisco M. The Need for a Conceptual Expansion of Neuroethics. AJOB Neurosci. 2019.

[183] Bassil K. Mending the Language Barrier: The Need for Ethics Communication in Neuroethics. American Journal of Bioethics Neuroscience. 2023.

[184] Rommelfanger KS, Ramos KM, Salles A. Conceptual conundrums for neuroscience. Neuron. 2023.

Recommendations: Towards an EU Neurotechnology Strategy

A thriving and trustworthy EU neurotechnology ecosystem would align with the new Commission's agenda to enhance competitiveness and drive innovation across strategic technology sectors, particularly in view of the forthcoming Biotechnology Act, as well as strengthening the European Health Union.

The EU could position itself as a global leader in neurotechnology — not least because neurotechnologies hold significant potential for advancing brain health, mental well-being, and healthy development and aging for current and future generations.

In order to achieve this, the EU must be committed to the **principles of anticipatory and participatory governance.** These are essential for ensuring that neurotechnology development and use progresses in a way that effectively addresses societal concerns while respecting fundamental rights.

Crucially, the EU has already laid political ground to be built on. In 2023, EU member states signed the León Declaration, marking their commitment to foster neurotechnology innovation within a framework that prioritises human rights, ethics, and transparency, and acknowledging the rapid pace of the technologies' development and the urgency of the technologies' societal implications. To turn this current political will and interest into further policy and action, **the EU needs to develop a strategy on neurotechnology that paves a policy path toward an ecosystem of trust for neurotechnology research, innovation, and use in Europe.**

This strategy must build on existing efforts in neurotechnology, such as the León Declaration, and its process of delineation should involve additional key principles laid out below, for each of which we suggest corresponding actions:

Principle 1

Anticipatory policymaking: fostering safe innovation and use through forward-looking policy

Keeping up with the rapid pace of innovation in the field of neurotechnology requires good foresight. Anticipatory governance enables policymakers to design more adaptive and future-proof regulations that can respond to future developments. Furthermore, by proactively evaluating potential risks and opportunities, the EU can target investments in technologies that not only advance innovation but also uphold ethical and regulatory standards. This proactive approach could support a sustainable ecosystem for neurotechnology, positioning the EU as a leader in neurotechnology while safeguarding the public and upholding trust and societal values.

Actions:

1. Conduct exploratory foresight-based analyses, for instance including scenarios, on the societal implications of current and future neurotechnologies to complement and support evidence-based policy-making.
2. Use the Better Regulation strategic foresight tool in policy impact assessments related to neurotechnology (including on related policy topics such as data, biotechnology, health, AI, etc.) to anticipate its long-term challenges and design policy accordingly.
3. Stress-test existing regulatory frameworks and future policy options against possible threats and disruptions, such as cybersecurity attacks or misuse of current and possible future neurotechnologies.
4. Create a direct link between foresight-driven insights on neurotechnology and EU innovation funding mechanisms such as Horizon Europe, particularly the European Innovation Council (EIC).

Principle 2

Inclusive and participatory policymaking: building trust and democratic legitimacy through meaningful stakeholder engagement.

Leveraging the full toolbox of participatory mechanisms for broad public engagement will strengthen transparency and public trust in neurotechnology governance, and consequentially neurotechnology as well. This includes both EU top-down and civil society bottom-up mechanisms, which should complement one another.

Actions:

1. The European Commission should launch a White or Green Paper with a stakeholder consultation, focusing on broad citizen engagement to address the ethical concerns of neurotechnology. This would ensure structured, transparent consultation with diverse public and private stakeholders.
2. Leverage multi-stakeholder civil society platforms in conjunction with the European Economic and Social Committee (EESC) and the Committee of the Regions (CoR) to discuss neurotechnology. These platforms would facilitate dialogue across local, regional, and sectoral perspectives, creating a space for ongoing feedback on the societal and ethical dimensions of neurotechnology.
3. Develop and deploy accessible engagement toolkits that help address the specific challenges of neurotechnology, by supporting value-driven conversations

[185] To date, this work has recently begun within the EU Institutions, for instance with a STOA study on mental privacy.

[186] The European Parliamentary Research Service has developed a methodology for stress-testing EU policies against threats and disruptions.

[187] The JRC has an ongoing collaboration with the EIC to support its funding prioritisation with strategic foresight-based intelligence.

among diverse groups. These toolkits should provide clear, practical guidance on stakeholder engagement, tailored to the complexities of neurotechnology governance. The Annex to this document provides a starting point.

4. Ensure transparency in participatory consultations by publishing public reports that clearly outline how stakeholder feedback has shaped policy decisions.

Principle 3

Clear and harmonised policymaking: frame concepts responsibly and illuminate grey areas.

This would promote clarity and consistency across jurisdictions, reducing regulatory fragmentation and making it easier for innovators to comply with standards. It would also facilitate ethical alignment and the protection of fundamental rights like privacy and autonomy, no matter where the technologies are developed or used. Additionally, it would support cross-border collaboration and foster a thriving European neurotechnology ecosystem through a genuine Single Market, reinforcing the EU's leadership in this rapidly evolving field.

Actions:

1. Develop a common taxonomy for neurotechnology: to avoid ambiguity, all stakeholders must share a clear and consistent lexicon of neurotechnology terminology. For example, ensure that terms like "personal data," "invasiveness", "public interest" are clearly defined. This taxonomy should be created in a participatory manner.

2. Review the existing toolbox of governance frameworks (both hard and soft), and identify areas where improvements can be made, such as addressing the grey areas in neurotechnology governance. For example, establishing best practices to tease out scientific evidence from "neurohype," the blending of medical and non-medical devices, the blurring of distinctions such as invasive and non-invasive; and the potential for empowerment versus exacerbation of vulnerabilities.

3. Identify and examine the underlying values (social, cultural, philosophical, political, ethico-legal) in the framing of neurotechnology and of the issues it raises.

4. Review existing engagement efforts and consider how framing shapes understanding of neurotechnology and implications and influences who participates and how their participation is enabled.

Such an **EU neurotechnology strategy** will need further elaboration, extensive co-creation, and continued stakeholder engagement in view of its implementation. In terms of substance, the strategy should prioritise projects aligned with **human flourishing and supporting brain health throughout the lifecourse**. This should include optimising existing technologies and supporting development of future technologie. Importantly, the strategy should promote exploring expanded uses of innovative neurotechnologies that can be adapted for multiple applications. For example, deep brain stimulation is established for movement disorders, but is being explored for depression, obesity, among others.

The strategy will need to to be **aligned with the priorities of the new Commission**, including the forthcoming Biotechnology Act, the implementation of the European Health Data Space, the prospects for further institutionalising the EU's Better Regulation agenda, the proposed Digital Fairness Act, among the many other policy tools and frameworks at hand. The EU will need to capitalise on its strategic foresight capacities and participatory frameworks and initiatives, including the proposed Civil Society Platform, to ensure this strategy is inclusive and collaborative at heart. We stand ready to support the EU's efforts toward inclusive neurotechnology governance.

Annex: Towards Inclusive EU Governance of Neurotechnologies

Table of key neurotechnology stakeholders

This table is not meant to be exhaustive, but rather give an indication of stakeholders that are especially relevant to neurotechnology policy dialogues and engagement efforts, and why.

Category	Stakeholder	Who they are	Why they're important
Users	Patients and people with lived experience of neurotechnologies	Individuals with lived experience of neurological or mental health conditions. They may or may not have used or be using neurotechnology, or similar types of treatment, to address specific health conditions.	They provide critical insights into the risks, needs, and preferences of users in a clinical setting, influencing both ethical considerations and practical usability.
	Consumers and enthusiasts	Individuals using neurotechnologies for non-medical purposes like well-being, focus tracking, gaming, or cognitive enhancement.	Their experiences can highlight issues around privacy, consent, and the broader ethical and social implications of everyday use of neurotechnologies.
	General public	Citizens whose social perceptions and expectations influence the broader acceptance and market adoption of neurotechnologies.	Their views shape societal trust and the broader regulatory and market landscape for neurotechnology adoption.
Researchers academia	Neuroscientists	Experts in the field of neuroscience with in-depth technical knowledge of the brain and the science behind neurotechnologies.	Their expertise ensures that policies are grounded in the latest scientific developments, potential benefits, and technological challenges in neurotechnology.

Category	Stakeholder	Who they are	Why they're important
	Neuro-ethicists	Specialists in neuroethics focused on the ethical dimension of and implications of neurotechnological developments throughout the technology's lifecycle.	They provide critical insights on how to integrate ethical and societal considerations—such as respect for privacy, autonomy, equitable access—into the governance and use of neurotechnologies.
	Social scientists and philosophers of mind	Experts in fields like philosophy, sociology, anthropology, and psychology, studying the implications of neurotechnology on identity, free will, and societal perceptions of mental health and enhancement.	Their perspectives bring to light underlying assumptions and enable exploration of notions of self, agency, humanness and whether and how they can be impacted by neurotechnology.
	Data privacy and cybersecurity experts	Since neurotechnologies involve handling sensitive neural data, these experts focus on identifying, investigating, and managing data breaches, hacks, and data misuse	Experts in this area ensure that policies safeguard personal data and protect against cyber threats.
	Technology and AI ethics experts	Focus on the ethical issues raised by the convergence of neurotechnology and AI	Ensure AI and neurotech ethics are integrated into governance frameworks to address issues like bias, manipulation, and decision-making.
Innovators and developers	Companies, startups, and engineers	Entities and individuals responsible for translating scientific research into practical neurotechnologies and bringing them to the market.	They shape the direction of neurotechnology by commercialising new innovations and play a key role in testing the feasibility of regulations and assessing their impact on innovation.
	Investors, funders and venture capitalists	Financial stakeholders that provide the necessary capital for neurotechnology research, development, and the growth of companies in the sector.	Their investment priorities influence which neurotechnologies receive funding, shaping the direction of innovation and market growth.
Healthcare professionals	Neurologists, psychiatrists, and psychologists	Healthcare professionals likely to use neurotechnologies in clinical settings to diagnose, treat, or support patients with neurological or mental health conditions.	They offer practical perspectives on integrating neurotechnologies into healthcare systems and patient care.

Category	Stakeholder	Who they are	Why they're important
	Bioethicists within healthcare systems	Specialists in medical ethics working within healthcare institutions, focusing on the ethical principles guiding patient care and the introduction of new technologies.	They help bridge the gap between neurotechnological innovations and medical ethics principles such as non-maleficence (do no harm), autonomy, and justice, ensuring that these technologies are introduced responsibly in healthcare settings.
	Global health experts	Specialists in public health who focus on improving healthcare access, particularly in low-resource settings across the world. They can offer valuable insights on the potential for neurotechnologies to either widen or reduce global health disparities.	Neurotechnologies, especially in healthcare, could significantly impact global health outcomes, but without careful oversight, they risk exacerbating health inequalities between high-income and low-income countries. Global health experts ensure that these technologies are integrated into equitable healthcare frameworks that benefit all populations.
	Patient engagement experts	Professionals in research, medicine, and engagement who integrate patient perspectives into clinical research and development processes. They help to prioritize patient input and elevate patients as active collaborators rather than passive participants.	More effective and meaningful therapies using neurotechnology are possible when research goals align with the needs and experiences of patients. These experts foster multi-stakeholder collaboration to improve healthcare outcomes and drive innovation that directly addresses patient quality of life.
Legal experts	Lawyers	Legal experts, especially those specialising in healthcare, technology, intellectual property, and human rights laws as they pertain to neurotechnology.	They help shape the legal landscape by addressing issues such as privacy, consent, liability, and personhood in the deployment and regulation of neurotechnologies.
	International law specialists	Experts in international law, focusing on cross-border health and technology and issues, particularly as these technologies often transcend national boundaries.	They address the cross-border implications of neurotechnological applications, such as data transfer, intellectual property rights, and international regulatory harmonisation.
Regulators and Policy Makers	Policy-makers	Government officials responsible for crafting legislation and governance frameworks that regulate neurotechnologies.	They ensure regulations are designed so that neurotechnologies are developed and deployed in ways that are ethical, safe, and responsible.

Category	Stakeholder	Who they are	Why they're important
	Regulatory bodies	Agencies responsible for regulating sectors such as medical devices and data protection (e.g., medical device regulators, data protection authorities).	They are key to developing adaptive legal frameworks capable of managing the rapid evolution of neurotechnologies, ensuring these technologies are safe, ethical, and comply with privacy regulations.
	Notified Bodies	Independent organisations designated by EU member states to assess the conformity of medical devices, including neurotechnologies, with EU regulations before they can be placed on the market.	They play a crucial role in ensuring that neurotechnologies meet the required safety and performance standards, particularly for medical devices, thus acting as gatekeepers for market access.
International Organisations and Multilateral Bodies	International Organisations	Global institutions such as the World Health Organization (WHO), United Nations (UN), and Organisation for Economic Co-operation and Development (OECD).	They play a key role in establishing global standards and ensuring harmonisation of neurotechnology governance across borders, addressing issues like safety, ethics, and data protection on an international scale.
	International Ethical Review Boards	Ethical review bodies at the international level that provide guidelines and oversight for research and development in fields such as neurotechnology.	They offer frameworks for conducting responsible research and development, ensuring that neurotechnology operates within ethical boundaries, focusing on inclusivity, human rights, and privacy.
Civil Society Organisation	Trade associations	Organisations representing industries and businesses involved in neurotechnology development and implementation.	They can provide valuable insights into market trends, innovation priorities, and regulatory needs from an industry perspective.
	Patient associations	Organisations that represent patients, particularly those using neurotechnologies for healthcare purposes.	They offer critical insights into the needs, risks, and experiences of those directly affected by neurotechnologies in medical contexts.
	Consumer rights associations	Organisations focused on protecting consumers, particularly in terms of privacy, consent, and the ethical use of neurotechnologies.	They safeguard public trust by ensuring neurotechnologies respect consumer rights and data protection.

Category	Stakeholder	Who they are	Why they're important
	Youth groups and organisations	Organisations representing youth, especially relevant as younger generations are likely to engage with emerging neurotechnologies in education, gaming, and mental health.	Youth perspectives shape the long-term societal impacts of neurotechnologies, particularly in areas like cognitive enhancement and digital interfaces.
	Professional associations, workplace rights organisations	Bodies representing professionals across industries and organisations advocating for workplace rights in the context of neurotechnology adoption.	They ensure that neurotechnologies introduced in workplaces respect labour rights, privacy, and employee well-being.
	Disability and anti-discrimination organisations	Organisations advocating for people with disabilities and those promoting anti-discrimination and inclusivity in neurotechnology development.	They provide perspectives on how neurotechnologies can be developed inclusively and how they impact accessibility and equity in society.
	Religious and spiritual organisations	Organisations representing religious and spiritual communities concerned with the ethical and philosophical implications of neurotechnologies.	They offer perspectives on how neurotechnologies intersect with beliefs about the self, consciousness, and free will, influencing broader societal acceptance.
	Environmental organisations	Organisations focused on the environmental impact of technological innovation.	They ensure that the development and use of neurotechnologies are aligned with sustainability and environmental responsibility.
	Civil rights organisations	Groups focused on protecting and promoting fundamental rights, such as privacy, autonomy, equality, and freedom of thought, particularly in relation to emerging technologies.	They ensure that neurotechnologies uphold civil liberties, prevent abuse, and address concerns related to privacy, consent, and mental integrity in their development and deployment.
Science Communications and Engagement	Journalists	Professionals responsible for reporting on neurotechnology developments, providing the public with transparent and accurate information.	They play a crucial role in shaping public perceptions of neurotechnologies, highlighting both their opportunities and risks, and ensuring accountability through investigative journalism.

Category	Stakeholder	Who they are	Why they're important
	Science communicators	Specialists in communicating complex scientific and technological developments to the general public in an accessible manner.	They help promote transparent and balanced reporting, making neurotechnology understandable and fostering public dialogue on both the opportunities and risks associated with these innovations.
	Science center engagement specialists	Professionals based in science centers who engage the public through interactive exhibits, workshops, and programs. They create spaces that facilitate dialogue between researchers, developers, and public participants.	Science centers serve as trusted hubs within the science ecosystem, and act as bottom-up engagement partners in neurotechnology research, development, and policy-making. These experts act as conveners, bridging diverse communities by engaging and collaborating with multiple stakeholders.
	Embedded engagement specialists	Experts embedded within labs, research centers, and industry who collaborate with science professionals to effectively engage public participants. They work directly within research environments to promote meaningful interactions.	These partners to scientists and engineers not only introduce neurotechnology to new audiences but also integrate public voices and concerns into scientific and technological processes. This approach enhances transparency and builds trust.
	Engagement and learning researcher	Researchers dedicated to understanding how public engagement methods promote learning and participation in science.	They help participants understand and document the value of public engagement with science through evaluation and research. These experts ensure that neurotechnology public engagement initiatives remain responsive to stakeholders and continue to improve over time.

Diversity for neuroethics

These are examples of dimensions of diversity of world-views to consider when creating inclusive, participatory processes. This is not to suggest that this involves all possible dimensions of diversity, nor that people can easily be put into each of these 'categories'. A single individual can hold a number of social identities.

Furthermore, while diversity is important, it should not be mistaken with inclusivity. A common pitfall of not recognizing this difference is tokenism. Inclusive processes often require professionals who are adept at creating spaces that enable exchange of ideas, humility, reflexivity, and an overall spirit of collaboration (see also Table. Attributes for Inclusive Neuroethics Engagement).

Category	Criteria	Why it's important	What to consider
Demography	Age / generation	Neurotechnologies have varying implications across age groups and generations. Younger people may engage with neurotechnologies for cognitive enhancement, gaming, or entertainment, while older adults may rely on these technologies for healthcare, rehabilitation, or managing age-related conditions.	Ensure multigenerational representation in discussions, considering how different age groups access and perceive neurotechnologies, such as diversity in ethical perceptions, values, access to technology, privacy concerns.
	Gender	Neurotechnologies may affect men, women, and non-binary individuals differently, both biologically and socially. Ensuring gender diversity in neurotech governance helps address issues of access, safety, and user experience, while also challenging any gender biases in research, design, and implementation.	Incorporate diverse gender perspectives when designing neurotechnologies, especially in areas such as health (e.g., mental health treatment or cognitive enhancement), where gender differences may influence outcomes. Also, ensure gender balance in panels, research teams, and stakeholder discussions.
	Ethnicity / race	People from different ethnic and racial backgrounds may have distinct perspectives and even technical considerations when using neurotechnologies, influenced by cultural, historical, and biophysical factors. Addressing these differences ensures that neurotech development is equitable and inclusive, preventing technologies from perpetuating existing biases or health disparities.	Acknowledge and address systemic disparities in access to healthcare and technology. Ensure representation so that neurotechnologies do not reinforce racial biases, especially in areas like neural data collection, mental health treatment, and AI algorithms in brain-computer interfaces.

Category	Criteria	Why it's important	What to consider
	Socio-economic status	Socio-economic disparities affect access to new technologies, particularly expensive or cutting-edge innovations, often creating disparities and inequalities.	Address the affordability and accessibility of neurotechnologies for lower-income groups. Evaluate how factors like education, income, and access to healthcare shape people's ability to benefit from neurotechnologies, particularly in healthcare and mental health applications.
	Educational level	Neurotechnology is a complex field, and stakeholders with varying levels of education—ranging from high school graduates to PhDs—will have different perspectives and understandings of the technology's implications. Involving participants across the spectrum of educational backgrounds ensures equitable participation and can lead to a broader range of insights on policy and governance.	Make information accessible and understandable, using plain language when discussing technical aspects. Also, tailor engagement strategies, such as educational workshops, to raise awareness and foster inclusivity.
	Minority groups, indigenous peoples	Minority groups and Indigenous peoples may have unique perspectives on neurotechnologies, shaped by their cultural, historical, and social contexts. Ensuring their participation in neurotech governance is critical for safeguarding their rights and preventing technologies from marginalising or exploiting vulnerable groups.	Understand how cultural values, worldviews, and historical experiences with technology influence their perspectives. Indigenous knowledge and ethical frameworks may provide alternative ways of thinking about neurotechnological innovation, particularly in relation to cognitive liberty and bodily autonomy.
	Intersectionality (multiple overlapping identities)	People often belong to multiple identity groups (e.g., a woman of color with a disability), and these overlapping identities could affect how they experience neurotechnologies.	It's important to ensure neurotechnologies are designed and governed with an intersectional lens, addressing issues of compounded marginalisation or exclusion.

Category	Criteria	Why it's important	What to consider
Neurodiversity	Neurodiversity across the spectrum	Neurodiverse individuals, including those with autism, ADHD, and other neurological differences, may interact with neurotechnologies in unique ways. By considering neurodiversity, we can ensure that neurotechnologies are inclusive and adaptable to a wide range of cognitive functions and processing styles.	Neurotechnologies should accommodate different sensory and cognitive needs, such as sensitivity to stimuli or alternative communication methods. It's essential to involve neurodiverse individuals in both the development and governance of these technologies to avoid bias or exclusion.
	Cognitive and neurological disabilities	Individuals with cognitive or neurological disabilities (e.g., dementia, epilepsy, or traumatic brain injury) may use neurotechnologies for healthcare or enhancement, but their needs must be addressed to avoid potential harms. Including these perspectives ensures that technologies are safe, effective, and aligned with ethical healthcare practices.	Recognise the unique healthcare needs of individuals with cognitive or neurological differences, such as accessibility in medical neurotechnology or cognitive enhancement tools. Consider potential ethical dilemmas, such as the balance between autonomy and care in vulnerable populations.
	Mental health perspectives	Neurotechnologies are increasingly used in mental health treatments, such as for depression, anxiety, and PTSD. It's critical to include mental health perspectives in governance to ensure that these technologies are effective, non-stigmatizing, and respectful of patients' rights.	Mental health conditions often carry stigma, so it's essential to ensure that neurotechnologies used in this context are developed and deployed in a way that respects patients' dignity and privacy. Consider how these technologies might shape public perceptions of mental health and how they are integrated into mental healthcare systems.
Geographic and cultural diversity	Global North and Global South	Countries in the Global North and Global South experience different levels of access to technology, healthcare, and innovation funding. While the Global North often leads in neurotechnology development, the Global South may face challenges in accessibility, affordability, and ethics of deployment. Including perspectives from both regions ensures a more equitable and globally aligned neurotech governance.	The Global South may have different healthcare needs and regulatory priorities compared to the Global North. Consider the ethical implications of exporting neurotechnologies to regions with different cultural, economic, and healthcare systems.

Category	Criteria	Why it's important	What to consider
	Geographic regions (continents and sub-regions)	Each region—Africa, Asia, Europe, Latin America, North America, and Oceania—has its own regulatory, political, and healthcare frameworks that influence the development and governance of neurotechnologies. Including representatives from various continents ensures that governance frameworks are responsive to the local needs and contextual challenges of each region.	Different regions may face unique challenges such as regulatory capacity, data privacy concerns, or healthcare infrastructure. Understanding these contexts is crucial for developing inclusive and globally relevant neurotech policies.
	Urban and rural	Urban areas tend to have better access to healthcare and cutting-edge technologies, while rural regions may face significant disparities in access to neurotechnologies. Ensuring engagement from both urban and rural populations can help bridge the gap and ensure equal access to the benefits of neurotechnologies.	Rural communities may have less infrastructure for neurotechnology but could benefit greatly from healthcare advancements. Urban areas may focus more on ethical concerns related to rapid adoption and data privacy, while rural regions may focus on accessibility and affordability.
	Cultural, ethical, and political beliefs	Neurotechnologies may challenge cultural and ethical norms related to mental autonomy, cognitive enhancement, and privacy. Respecting diverse political, ethical, and religious values is critical for building trust and ensuring that neurotech governance is aligned with local beliefs.	Different cultures and political systems have varying perspectives on issues like cognitive liberty, mental privacy, and biotechnological intervention. It's important to adapt neurotechnology policies to local moral frameworks and governance systems.

Example neuroethics engagement methods

Method	How it works	When to use it
Neuro Futures Card Game[1]	A deck of cards featuring potential future neurotechnologies, inspired by real products and emerging trends. Technologies can be paired with prompts and provocations that challenge participants to consider the unexpected impacts, reflecting on their own values as well as those of others	The activity can be deployed in many different contexts, including co-creation workshops, scenario workshops, panel discussions for audience engagement, etc. This activity is designed as an open-ended, conversational experience aimed at facilitating self-reflection, reflexivity, and dialogue among participants.
What Makes Us Human Game[1]	In this game, participants rank abilities from most to least uniquely human, then assign them to robots for specific jobs, reflecting on their creations. They are encouraged to share their values on what defines human identity—ranging from creativity and morality to senses and emotions—while considering the future implications of AI.	This game works well in informal group discussions, offering a creativity-rich approach to exploring end-of-life issues and the evolving relationship between humans and machines. With simple materials, participants are gently introduced to complex topics of human identity and cognition, mirroring the considerations raised in neurotechnology
Brain Enhancement Conversation Lab[1]	In this program, participants explore the ethics of brain enhancement, such as using electrical devices to boost brain function. After learning about current technologies from a local expert, small groups use a drawing exercise with symbols to reflect on how their values might shape individual and societal decisions.	This program helps connect researchers with engaged communities, fostering a welcoming environment where diverse viewpoints are respected. Creativity and collaboration drive participants' discussions and stories as they navigate decisions about using neurotechnologies.
Neuroethics hackathon[2]	A structured experience that brings together neuroscience professionals to work together to propose solutions to complex ethical, legal, and social challenges surrounding emerging neurotechnologies. Teams with diverse perspectives select future neurotechnologies as the basis of a new company's strategy promoting responsible innovation using international tools and guidelines.	This program targets early and mid-career professionals, many of whom may be encountering neuroethical questions for the first time. The hackathon provides a safe space outside the lab to raise ethics awareness and facilitates diverse groups in co-creating socio-technical solutions to complex governance challenges.

[1] From the NISE Network found at nisenet.org/brain. Evaluation of these methods is included in (Anderson, A. (2023). Changing Brains: Formative evaluation report.)

[2] From the IoNx Think and Do Tank, prototyped during the 2024 FENS Forum.

Attributes for inclusive neuroethics engagement

Adapted from Das et al, 2022.

1. Humility: Initiating and pursuing neuroethics engagement requires humility both epistemically and morally. On the one hand it is an epistemic consideration that recognizes the limits and promises of science and technology and their outcomes . On the other hand it is a moral consideration that recognizes the value of other sources of generated knowledge and their contribution to issues in science and society.
2. Openness: Openness in neuroethics engagement creates a context for transparent sharing of perspectives as well as curiosity that can facilitate generative and authentic exchange of ideas. Openness invites the voices of other groups (i.e. disciplinary, social, cultural) to participate in neuroethics engagement activities and learn from them.
3. Reflexivity: Science and society are value-laden. These values can dictate the commitments assumptions and consequences of research in both neuroscience and neuroethics. Reflexivity allows a self-exploration of biases and presents an opportunity for publics to engage in reflective practice together in a way that sheds light on respective ideological commitments and assumptions while recognizing where they converge and diverge.
4. Intellectual Agility: Neuroethics engagement with a commitment to actionable outcomes requires real-time intellectual agility that allows agents to (a) adapt to new goals or constraints of the engagement experience (b) respond to different perspectives and (c) cultivate willingness to iterate, learn and reimagine one's stance and values
5. Creativity: Thinking creatively is at the foundation of scientific research and can embolden interdisciplinary teams exploring ethical implications of current and future innovations. Importantly creativity is not necessarily inherent but instead a skill that can be practiced and developed throughout life. Fostering creativity in participants through moral imagination (a blend of creativity and ethical thinking) is a type of creative cultivation which can enhance empathy perspective-taking and even facilitate quick ethical decision-making when needed.
6. Cultural Curiosity: Proactive exploration of culture understood broadly e.g. in the disciplinary and geographical sense not only of one's own culture and others. A key consideration for neuroethics is how conceptions of the relationship between the brain and mind, cognitive experience, memory, identity, autonomy, and agency and how they impact personal and societal ethical evaluations on the value conflicts that might arise with emerging neurotechnology.

ABOUT IONX:

The Institute of Neuroethics is the first international think-and-do tank wholly dedicated to neuroethics. Striving for systems level change, IoNx works with builders, decision makers, and users to empower a world with trusted neuroscience for all.

ABOUT ICFG:

The International Center for Future Generations is an independent think-and-do tank dedicated to shaping a future where decision-makers anticipate and responsibly govern the societal impacts of rapid technological change, ensuring that emerging technologies are harnessed to serve the best interests of humanity.

ACKNOWLEDGEMENTS:

The authors are grateful to the many colleagues, experts, and stakeholders who contributed to this work in diverse ways, including participation in our workshops, interviews, exchanges, and review of the present document.

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