EBC
European Brain Council

European Charter for the Responsible Development of Neurotechnologies

Neurotechnologies

Over the last decades, advances in technology and in the understanding of the human nervous system have expanded the possibilities of using such knowledge under the form of devices and procedures, collectively referred to as neurotechnologies. Neurotechnologies are designed to interact with the brain and nervous system, providing support for the diagnosis, monitoring, and treatment of neurological and mental health conditions, thereby addressing unmet medical needs and promoting brain health globally. Beyond their clinical utility, neurotechnologies are being mobilised in a growing number of settings beyond health and research, including education, the workplace, and the direct-to-consumer market for entertainment and personal use.

In 2021, 3.4 billion people had a condition affecting the nervous system, corresponding to 43% of the world's population. As populations continue to grow and age, the prevalence and burden of brain disorders are bound to increase, driving a heightened focus on prevention of brain disorder and the promotion of brain health. Brain health is defined as the state of brain functioning across cognitive, sensory, social-emotional, behavioural and motor domains, enabling individuals to realise their full potential over their life course, irrespective of the presence or absence of disorders. Neurotechnologies have great potential to foster brain health. Clinical tools range from Magnetic Resonance Imaging (MRI) and Electroencephalography (EEG) to Deep Brain Stimulation (DBS), each holding transformative power for both diagnosis and management of neurological and mental health conditions.

Furthermore, the growing accessibility and portability of neurotechnologies, along with their potential applications in everyday life, have expanded their use beyond the medical field and into the general consumer market (for example in work, education, entertainment, and marketing). Consequently, over the past decade, the field of neurotechnology applications has grown exponentially, with the neurotechnology market projected to reach more than $24 billion by 2027.

However, the uses of neurotechnologies both in the medical field and the general consumer market raise crucial ethical and societal issues—notably in terms of human enhancement, regulation and marketing of direct-to-consumer devices, protection of personal neural data and vulnerability of cognitive patterns for commercial or political manipulation.

International context and European regulatory landscape

The field of neurotechnologies is advancing rapidly, fuelling global debate over their research, development, use and regulation. Various binding and non-binding mechanisms of governance are available to policymakers and other stakeholders—including laws, regulations and recommendations.

Adopted in 2019, the Organisation for Economic Co-operation and Development (OECD) recommendation #457 on Responsible Innovation in Neurotechnology constitutes the first international standard in the field. The United Nations Educational, Scientific and Cultural Organization (UNESCO) report on the Ethical Issues of Neurotechnology (2021) was a landmark publication, and the upcoming UNESCO Recommendation on the Ethics of Neurotechnology (2025), as well as the work of the European Group on Ethics in Science and New Technologies, are set to further enrich the debate.

Launched under the Spanish Presidency of the Council of the EU in 2023 and resulting from an agreement by EU's telecommunications and digital ministers, the León Declaration on European Neurotechnology represents a first move to protect digital rights in the development of neurotechnologies at the European level.

Although the EU still lacks specific regulations and directives dedicated to neurotechnologies, the Medical Devices Regulation (MDR), the General Data Protection Regulation (GDPR), the EU consumer protection law (the Unfair Commercial Practices Directive) and the more recent European Artificial Intelligence Act (EU AI Act) already provide baseline levels of consumer protection and general product safety standards relevant to the development of neurotechnologies in the EU.

Medical and non-medical applications

Medical devices, defined in the Medical Devices Regulation, cannot be placed on the European market without conforming to strict safety requirements including the affixation of the CE marking of conformity—indicating that *a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.*

Non-medical applications include products for neurostimulation and neurofeedback in work, education, entertainment and marketing. These devices often lack appropriate oversight regarding their scientific foundations, safety, efficacy and ethical supervision: for instance, EEG systems with an intended medical purpose require a pre-market approval, while EEG direct-to-consumer products are only subjected to the CE marking of conformity.

Despite European regulations and international recommendations, significant gaps and grey areas persist in the governance and development of neurotechnologies. For instance, the protection of personal neural data warrants additional safeguards in data privacy regulations (transparency of collection, processing, sharing and use of personal neural data) because of the unique role of the brain in governing cognitive processes and personal identity. Furthermore, direct-to-consumer devices require clear guidelines for responsible development, respecting individual rights regarding mental privacy and informed consent; connected devices must adhere to rigorous hardware, software and data security measures to protect against potential cyber threats; and life-long continuity of care for persons with neuro-prostheses should be systematically ensured.

About the European Charter for the Responsible Development of Neurotechnologies

In order to fill these gaps, the European Brain Council (EBC) convened stakeholders from across the EU brain community to discuss ethical and social challenges raised by neurotechnologies, resulting in the establishment of a Task Force for the elaboration of a European Charter for the Responsible Development of Neurotechnologies.

This Charter was jointly elaborated by diverse stakeholders in the field and its content emerged from collaborative dialogues between public and private sectors. Through a public consultation, the Task Force also gathered insights and feedback from various age groups and stakeholder categories across Europe. The Charter reflects a bottom-up, co-creative approach, bringing together key stakeholders in the European brain ecosystem, including organisations of people living with brain conditions, organisations of professional actors in health, research and ethics, policymakers, small and medium-sized enterprises.

At the national level, only a few countries have implemented frameworks specifically designed to protect individual and collective rights in the context of neurotechnologies. This includes France, which in 2022 implemented the OECD Recommendation 457 on Responsible Innovation in Neurotechnologies in the form of the French Charter for the Responsible Development of Neurotechnologies.

Value of a Charter

A charter functions as a non-binding agreement that offers a more agile and flexible governance framework, which is especially beneficial for swiftly changing technologies:

- Charters can be implemented with minimal bureaucratic hurdles or delays and can be updated more quickly and more efficiently than regulations.
- As the commitments outlined in charters are not limited by geography, they often possess a global dimension.
- Charters foster collaboration among a diverse range of stakeholders who might otherwise be more inclined to oppose each other in conventional regulatory contexts.
- Charters provide a consensus framework spanning researchers, innovators, policy makers and civil society (while regulations typically have a narrower target audience).
- Charters are not only complementary to other binding and non-binding laws, but they also constitute a guideline for development of novel governance tools and enhance consistency between different legal jurisdictions.

With the ultimate goal to promote a culture of stewardship and trust in neurotechnologies, to foster greater wellbeing and sustainable economic growth, and to guide public policy, business practices and investments, the European Charter for the Responsible Development of Neurotechnologies builds upon and complements existing mechanisms of governance and legislation by contributing to human-centred risk evaluations, addressing gaps and shedding light on grey areas deserving public attention and robust governance.

In particular, the Charter refers to:

- Compliance with all provisions of the GDPR as outlined in the TechDispatch from the European Data Protection Supervisor with respect to Proportionality and data minimisation, to Data accuracy, to Transparency and to Fairness.
- A general principle of prohibition on manipulative practices, in particular those below the threshold of consciousness, aligning with the EU AI Act:
  - Prohibited AI practices: AI system that deploys subliminal techniques (art. 5.1.a) and AI systems that exploits the vulnerability of a natural person (art. 5.1.b).
  - The guidelines of February 2025 of the European Commission on Prohibited AI Practices.
  - Compliance with all high-risk AI obligations (art. 6 and subsequent) when AI-based neurotechnology is integrated into a medical device, a toy, or when it is used in the biometrics, education, employment or justice sectors.
  - Principle of a ban on social scoring, emotional inference in the workplace and education (art. 5.1.c,d,f)
- Compliance with article 50 of the EU AI Act (Transparency obligations for providers and deployers of certain AI systems)

Given the rapidly expanding nature of neurotechnologies, the Charter is designed as a dynamic document, subject to regular review and updates.

Aims

The Charter aims to provide ethical guidance for the successful development of neurotechnologies in Europe by:

- Promoting equality of access and encouraging responsible, human-centred and rights-oriented innovation and business conduct,
- Protecting individuals, communities and vulnerable populations against any abuse or misuse affecting notions of human identity, freedom of thought, autonomy, privacy and human flourishing,
- Informing the general public, industry, scientific and clinical practice as well as policymaking,
- Supporting the economic growth of the field by strengthening trust between all actors and promoting societal deliberation and citizen participation.

Scope

The Charter covers all technologies, procedures and applications, medical and non-medical, that are designed and used to access, monitor, investigate, assess, manipulate and/or emulate the structure and functions of the neural systems of natural persons.

Glossary

The definitions used in this document are an adaptation of those of Organisation for Economic Co-operation and Development (OECD) recommendation #457 on Responsible Innovation in Neurotechnology adopted by the OECD Council of Ministers on 11 December 2019.

- **Abusive**: involving bad or wrong use of a device or a procedure used by someone, especially for the advantage of the technology provider.
- **Actors**: public and private organisations, and individuals who play an active role in neurotechnology innovation, including research, development, uptake, regulation, marketing and use.
- **Autonomy**: the freedom to make one's own choices.
- **Health**: a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
- **Neural data**: data relating to the functioning or structure of both the central and peripheral nervous system of an identified or identifiable individual that includes unique information about their physiology, health or mental states.
- **Neurotechnology**: devices and procedures used to access, monitor, investigate, assess, manipulate and/or emulate the structure and function of the neural systems of natural persons.
- **Safety**: an acceptable level of probable benefits and risks to health.
- **Stakeholders**: all organisations and individuals involved in, or affected by, neurotechnology, directly or indirectly. Actors are a subset of stakeholders.

European Charter for the Responsible Development of Neurotechnologies

Recognising the right of users, including people with a brain disorder, to preserve their human identity and freedom of thought; the right to inviolability of thought in non-life-threatening situations, bodily and neural autonomy and mental privacy; the right to oppose any non-consensual or abusive use of their data (including neural) and to refuse any non-consensual or abusive manipulation of their brain; signatories of the Charter make the following short- and long-term commitments.

First and foremost, the signatories commit to request a consent providing information written in clear, plain language, providing transparency not only about neural data collection and processing implications (more details in the section on data protection), but also about the overall implications of the use of neurotechnological devices and processes including but not limited to neural implants, the interactions with the neural system and the potential secondary effects. Clear, evidence-based educational material, prior to consent, should also be provided on the purpose, operation, risks, limitations and benefits of the neurotechnological devices.

Persons in situations of vulnerability

- Establish mechanisms for identifying contexts in the development or use of neurotechnologies in which individuals or populations become vulnerable; and mechanisms for identifying challenges, overcoming specific difficulties and addressing specific needs of populations at risk of physical, psychological or sociological vulnerability or stigmatisation.
- Engage proactively with persons in situations of vulnerability (individuals at risk of enduring physical, psychological or social harm, including stigmatisation) or their representatives throughout the entire life cycle of neurotechnology.
- Adopt best practices for inclusivity, diversity and age-appropriate design of neurotechnologies.

Reliability, safety, security and long-term support
(in compliance with all high-risk AI obligations – art. 6 and following of the EU AI Act)

- Establish industry standards which promote the effectiveness and safety of neurotechnological devices and processes, supported by scientific evidence. Continually assess risk of misuse and risk to fundamental human rights, monitored by on-going studies.
- Consider short-, mid- and long-term consequences of neurotechnology by establishing robust auditing, reporting and monitoring procedures.
- Ensure transparency regarding the evidence supporting claims of safety and efficacy to the extent possible.

- Use best available practices to secure devices and processes against external intrusion and manipulation.
- Aim to ensure the safety of neurotechnology considering both the device technology and its direct and indirect effects on users and bystanders.
- Seek and consider the feedback and comments of users of neurotechnology. Consider including a user representative in the research/production team.
- Use best available practices to ensure reversibility and avoid unexpected adverse effects of implantable devices or life-supporting technologies. Ensure responsibility is taken for the life-long functioning of neural implants and prostheses.
- Devise approaches to optimise short- and long-term compatibility, repairability and replaceability of hardware and software components of neurotechnological systems, in particular in the case of implantable devices and life-supporting technologies. This should include promoting mechanisms to ensure and incentivise availability of spare parts and detailed information about technology and procedures, in the event of end-of-life of neurotechnologies.

Prevention of misuse, malicious applications and manipulation
(in compliance with art. 5.1.a, c,d,f, art.6 and subsequent of the EU AI Act)

- Prevent the development of applications that result in any surveillance and/or evaluation of a person without prior consent.
- Prevent the abusive manipulation of neural states (temporarily stable regional brain activity patterns) or functioning, affective and cognitive functions or behaviour of users.
- Desist from developing and implementing non-medical applications and uses of potentially harmful neurotechnologies. In case of non-medical applications, the greatest attention should be paid to verify the innocuity of the neurotechnology, including at long-term. Clear information about what is known and how the information was obtained should be easily available and updated as novel evidence accumulates. In the case of medical applications, the benefits should be carefully considered and all possibilities for risk should be taken into account.
- Anticipate and block activities intended to influence the decision-making processes of individuals or groups by deliberately limiting autonomy or self-determination.
- Adopt an ethical approach to the development of neurotechnologies regardless of its application (whether research, medical or non-medical).
- Until safety standards are fully defined and implemented and a general European consensus is reached within society ensuring that no discriminatory practices arise from their use, prevent the use of invasive Brain Computer Interfaces, including neural implants, for the therapeutic purpose of improving the neural capacity of subjects without qualifying medical conditions. Call for vigilance on non-invasive technologies having similar purposes.

Establishment of mechanisms for oversight and monitoring
(in compliance with Annex I and Annex II of the EU AI Act)

- Establish transparent and effective mechanisms for identifying and documenting adverse events and provide clear and accessible mechanisms for redress.
- Implement good practices and standards on technical and non-technical risk management and impact assessment methods, including specific provisions on the application domain and related technologies.
- Support and promote regulatory stewardship to allow timely anticipation and assessment of potential misuse of neurotechnologies.

Protection of neural data
(in compliance with Data protection requirements and principles in the TechDispatch from the European Data Protection Supervisor – EDPS)

- Recognise neural data as personal and sensitive data, including recordings, physical measurements and any other data accessed, recorded or inferred by a neurotechnological devices/procedures or in combination with them. This includes the information obtained indirectly from monitoring movements, heart rate, eye modifications, skin conductance and other types of bodily reactions.
- Recognise the users' right to refuse the sharing of their neural data and reinforce the quality of information and the terms of consent, prior to data collection and storage.
- Provide users with clear, accessible and rigorous information on the collection, processing and use of neural data as well as on the storage, dissemination and sharing of such data.
- Require informed consent and explicit opt-in on the part of the user, for both software and hardware updates, presented in a way that is both accurate and understandable by the user.
- Ensure all reasonably practicable measures to meet the requirements of open science and prevent malicious re-identification such as fully anonymised data, pseudonymisation or minimisation.
- Protect the confidentiality of stored, transmitted or otherwise processed data, personal or other, with state-of-the-art tools such as encryption and specifically favouring privacy-preserving processes such as local data storage and edge computing.
- Use best practices to delete or modify, upon request, the neural data collected, with the exception of data already used for research purposes, and which have been anonymised, pseudonymised or minimised and shared with the scientific community – including but not limited to the GDPR, which should include special provisions for neural data (namely with regards to transparency of collection, processing, sharing and use).
- Ensure data portability. Ensure users can receive and transmit their neural data in a structured, commonly used, and machine-readable format.
- Refrain from using neural data or any BCI for marketing purposes without explicit informed opt-in consent.

Enhancing education in neurotechnology and their ethical implications

- Develop or integrate existing educational programs tailored for diverse stakeholders involved in the development of neurotechnologies (including academic and healthcare institutions and professionals, private sector companies, policymakers and patient advocacy groups) to enhance their understanding of neurotechnologies advancements and their regulatory and ethical implications, responsible research and development as well as the specific risks incurred by people with implanted devices (e.g., the proximity to electromagnetic interference).
- Collaborate with academic institutions to integrate neurotechnology ethics and responsible innovation into relevant curricula and research programs.
- Promote the adoption of ethical analysis in neurotechnology conference and journal publications.
- Encourage the establishment of independent community ethical standards bodies within the neurotechnology space.
- Develop recommendations for the private sectors to implement internal training and capacity-building initiatives designed to address the ethical implications relevant to their field of operation.
- Implement training modules for regulators and policymakers to enhance their understanding of neurotechnology advancements and their regulatory implications.
- Enhance transparency and public engagement by promoting neurotechnology literacy within the general population through workshops, seminars and public consultations. Such initiatives will also facilitate gathering of diverse perspectives on neurotechnology use and governance.
- Establish guidelines and educational resources for people living with a brain disorder and the general public to promote awareness of the benefits, risks and ethical considerations related to neurotechnologies.

Support of the neurotechnology development

- Encourage funding agencies to support responsible and ethical neurotechnology development; encourage regulatory mechanisms that promote ethical development of neurotechnologies and do not inhibit responsible innovation; encourage neurotechnology innovators to align with the Charter.
- Promote collaborative developments and financing in neurotechnologies and unlock access to data supporting such initiatives.
- Promote public and authorities understanding of neurotechnologies by providing educational resources and positive messaging.

Ethical communication around neurotechnologies
(in compliance with all the provisions of the GDPR summarised in the TechDispatch of the European Data Protection Supervisor - EDPS)

- Encourage open dialogue: create platforms for ongoing conversations among stakeholders, including citizen's groups, through forums, workshops and online discussions, to facilitate a culture of transparency and trust and to ensure diverse inputs are taken into account in decision-making processes, policymaking and governance. Additionally, inform the public debate on the long-term implications and trajectories of neurotechnologies.
- Make every effort to avoid raising unrealistic expectations or, conversely, unfounded fears concerning neurotechnologies.
- Foster interdisciplinary collaborations and educational initiatives to facilitate knowledge sharing and ethical decision making among stakeholders.
- Ensure transparency about the inputs, outputs and intentions of algorithms.

Taking societal values into account

- Promote inclusivity by ensuring that as many people as possible have access to the products and services developed.
- Exercise special vigilance to detect applications leading to discrimination and communicate on the means implemented to prevent them.
- Recognise, in the design phase, the need to anticipate potential abuses and apply ethics by design procedures with considerations to the RAD (Reflexivity – Anticipation – Deliberation) approach.
- Encourage development of applications which primarily meet a societal need or provide a direct societal benefit.
- Foster the development of neurotechnologies for health, particularly in the mental health area.
- Ensure that training data reflects the diversity of the population and avoid inherent bias.

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About the European Brain Council

The European Brain Council (EBC) is a network of key players in the "Brain Area", with a membership encompassing scientific societies, patient organisations, professional societies and industry partners. A non-profit organisation based in Brussels, its main mission is to promote brain research with the ultimate goal of improving the lives of the millions of Europeans living with brain conditions, mental and neurological alike.

With the aim to speak with one voice, EBC stands as the platform to foster cooperation between its member organisations and other stakeholders, consistently promoting dialogue between scientists, industry and society. As showcased by its growing portfolio of projects, research and policy papers, as well as events, EBC emphasizes the importance of continued interaction with the European Institutions to build strong European health policies, raising awareness and encouraging education on the brain and the repercussions of neurological and mental health conditions on society as a whole.

The **European Charter for the Responsible Development of Neurotechnologies** is a policy-driven project complementing EU consumer protection and general product safety standards. Acknowledging the unique role of the brain in governing cognitive processes and personal identity, the Charter refreshes the European policy debate on technology governance by promoting a culture of stewardship and trust in neurotechnologies, supporting greater wellbeing and sustainable economic growth, and guiding public policy, activities of companies and investments.

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Move for Your Brain

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