

LEÓN DECLARATION ON EUROPEAN NEUROTECHNOLOGY: A HUMAN CENTRIC AND RIGHTS- ORIENTED APPROACH

Neurotechnology refers to devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of animals or humans¹. It stands out as one of the most promising technologies of our time due to the wide range of opportunities it offers for new treatments and preventive medicine for people suffering from mental and neurological illnesses such as Alzheimer's disease. This technology encompasses a wide variety of practices and tools, including invasive techniques with internal implants inside the body, such as certain brain-computer interfaces (BCIs), closed loop neurofeedback, and non-invasive methods, some of which have already been in use for a long time, such as Magnetic Resonance Imaging (MRI), ElectroEncephaloGraphy (EEG)² and Transcranial Magnetic Stimulation (TMS). While it is important not to overlook potential challenges of invasive neurotechnologies, in this declaration, we will focus primarily on non-invasive techniques.

Non-invasive and non-medical applications of this technology also present a new opportunity to transform education, well-being, or entertainment through neurostimulation or brain modulation and stimulation, among others. They could enable companies to innovate, offering a more efficient and comprehensive education and a complete and immersive (or mixed) entertainment experience. However, the further development of neurotechnology raises crucial questions that require a debate, for example when it comes to respecting human rights.

The international community and interested stakeholders globally are debating the research, design, development, use, and decommissioning of neurotechnologies. Since 2019, the United Nations Educational, Scientific and Cultural Organization (UNESCO) has stressed the growth of neurotechnology and its intersection with Artificial Intelligence and the need for ethical oversight to protect human rights. Following a resolution of the United Nations Human Rights Council³, the Office of the High Commissioner for Human Rights also launched in 2023 the preparation of a study on neurotechnology and human rights⁴. At the Organization for Economic Cooperation and Development (OECD), Member Countries adopted a "Recommendation on Responsible Innovation in Neurotechnology" in December 2019⁵. The Council of Europe has been working on the intersection between neurotechnologies and human rights, from assessing whether the existing human rights framework is fit for purpose, including in its biomedical applications, and proposing the ethical principles to be followed in the development and application of neurotechnology⁶.

In the European Union, the discussion among Member States is in its nascent stage, also following the European Commission's new strategy for Web 4.0 and virtual worlds⁷. With this declaration and under the auspices of the Spanish Presidency, Member States initiate a reflection on the promotion of human-centric neurotechnologies that take fundamental rights into account.

Fostering the neurotechnologies ecosystem

The European Union has funded research and development of neurotechnologies through Horizon 2020 and Horizon Europe in priority areas such as development of neural prostheses, neurostimulation, neuroimaging, robotics and artificial intelligence applied to neuroscience⁸. Many governments as well as companies are investing heavily in neurotechnologies as organisations race to innovate, scale and secure market share.

Several governments around the world are investigating human rights implications of using neurotechnology to explore the potential of the human brain⁹. This interest goes beyond government spheres, as the private sector is also actively investing in this field. In particular, the market for BCIs experienced a remarkable increase last year, with a significant share going to non-invasive technologies¹⁰. This boom was driven by technological advances and the growing interest in integrating such interfaces into the gaming and entertainment sectors.

This international race will influence the future of many sectors, including virtual worlds, Europe has the opportunity to be at the forefront in this area.

European human-centric and rights-oriented neurotechnologies

Non-invasive neurotechnologies, such as wearable devices, can be used to connect our brains to computers, allowing us to participate with our five senses in virtual worlds, or improving our brain functions. Consumers can easily access them online or in specialised shops.

However, their proliferation and use raise important social, legal, ethical, cybersecurity and health issues. Specifically, there are consumer rights and privacy implications as well as critical health implications to consider, both in terms of physical and mental effects on individuals and the broader public health consequences. Manipulating, collecting, retaining, processing, and storing brain data¹¹ is of utmost sensitivity. For example, the analysis of consumer contracts of the world's 30 largest neurotech companies shows that every company processed all user's brain data, through consent mechanisms, and all but one was given permission to share with third parties¹². This could result in the accumulation of such data by a few companies. In the absence of specific safeguards, they could potentially violate people's privacy and/or influence people's thoughts and behavior, whether intentionally or unintentionally. This opens the door to a new mechanism for cyberattacks and for spreading disinformation, imperilling the democracies in which we live and posing a threat to the fundamental rights to human dignity, right for private and family life, protection of personal data, freedom of thought and respect for physical and mental integrity.

Various actions are unfolding both at the European and national levels to address the emerging challenges. While the EU has done extensive work in putting forward a solid legal framework for the digital world, aligned with the European Declaration of Digital Rights and Principles¹³, Member States are also forging their own pathways to tackle the issues at hand.

Therefore, Member States signing this declaration, in their commitment to strengthen up EU's competitiveness on neurotechnology and its open strategic autonomy in a digital transformation that is human-centric and rights-oriented, call for action to:

- **Encourage public-private co-operation** for the development of rights-oriented, evidence-based and cybersecure neurotechnologies. This co-operation aims to tackle and protect against pressing societal and human challenges, particularly in health, while fostering innovation in education, well-being, and entertainment.
- **Nurture a dynamic ecosystem** that allows to close the gap between research, innovation, and the market, to move from prototypes to products, aligned with fundamental rights as well as cybersecurity standards.
- **Consider accompanying and investment measures** in neurotechnologies through incubators and accelerators of neurotech in the EU as well as through venture capital investment or guarantee funds at seed and growth stages. It is essential to note that this declaration does not imply any financial commitment on the part of the Member States.
- **The European Commission**, in close cooperation with the newly established European Centre for Algorithmic Transparency¹⁴, **to facilitate specialised high-level expert discussions** to assess the degree to which the existing regulatory and policy frameworks, including those legislative proposals to be adopted soon, safeguard individual and collective rights in the context of neurotechnologies, possibly within the context of the Commission's work on Web 4.0 and virtual worlds. Based on the assessment, it is proposed to outline possible next steps to provide further guidance.
- **Foster dialogue with the European Commission and among Member States** ahead of international discussions on important issues of common interest in neurotechnologies.
- **Compel European neurotechnology innovators** to be aware and adhere to a human-centred and rights-oriented approach by design and by default in the development of their products.
- **The EU to actively inform and involve the public** in the debate on the opportunities, and risks of neurotechnology, for example, by conducting public consultations.
- **Create a trustworthy, transparent, and accountable ecosystem** for EU-citizens to use neurotechnology.
- **The European Commission to collaborate with standardisation bodies** to explore the need for the creation of standards for neurotechnologies, including cybersecurity standards with a focus on upholding human rights.

It is important to be proactive and act now to allow the EU to become a major player in nascent markets related to neurotechnologies by fostering innovation and promoting investments, in line with EU values and norms including the Charter of Fundamental Rights as well as the recently signed European Declaration on Digital Rights and Principles and thereby ensuring a human-centric and rights-oriented approach to protect

and empower people.

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