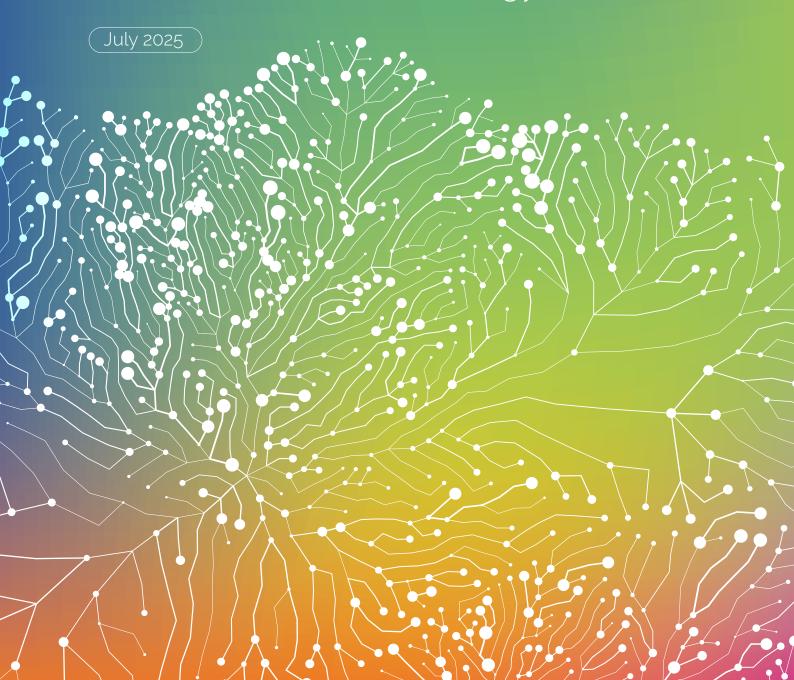


Neurotechnology Toolkit

To support policymakers in implementing the OECD Recommendation on Responsible Innovation in Neurotechnology



INTRODUCTION

The **OECD Recommendation on Responsible Innovation in Neurotechnology** [OECD/LEGAL/0457] is the first international standard in this domain.

It defines neurotechnology as "devices and procedures used to access, monitor, investigate, assess, manipulate and/or emulate the structure and function of the neural systems of natural persons." It aims to guide governments and innovators to anticipate and address ethical, legal and social challenges raised by novel health-related neurotechnologies while promoting innovation.

The OECD Neurotechnology Recommendation consists of **nine Principles**:

- (1) promote responsible innovation
- (2) prioritise safety assessment
- (3) promote inclusivity
- (4) foster scientific collaboration
- (5) enable societal deliberation
- (6) enable capacity of oversight and advisory bodies
- (7) safeguard personal brain data and other information
- (8) promote cultures of stewardship and trust across the public and private sectors and
- (9) anticipate and monitor potential unintended use and/or misuse.

Since its adoption in 2019, 39 countries have adhered to the OECD Neurotechnology Recommendation.

This Neurotechnology Toolkit aims to support Adherents in their implementation of the Recommendation.

Learn more about the Recommendation's history and implementation

Discover the navigation of this Toolkit

Read more on the OECD Neurotechnology Recommendation

RECOMMENDATION'S HISTORY AND IMPLEMENTATION

The Recommendation developed out of a step-wise process of structured consultation and engagement with policymakers, key stakeholders and civil society over the course of five years (2015-2019).

A steering group composed of delegates from the OECD Committee on Scientific and Technological Policy's (CSTP) Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) provided guidance throughout, including in the textual development of principles for responsible innovation in neurotechnology and their embodiment in the Recommendation. The steering group also conducted a series of workshops with expert participants from different disciplines and sectors, including government, academia, healthcare, civil society, business and philanthropy.

Since the Recommendation's adoption in December 2019, implementation activities have aimed to build capacity of Adherents and other stakeholders to put the Recommendation and its Principles into action.

September 2020	Seoul Event (virtual) "Building Capacity to Implement the OECD Recommendation on Responsible Innovation in Neurotechnology". Access <i>the report</i> .
May 2021	Zurich Event (virtual) "Neurotechnology in and for society: deliberation, stewardship and trust" to discuss ways in which to develop trust across the public and private sectors and deliberative practices through the implementation of Principles 5 and 8 of the OECD Recommendation on Responsible Innovation in Neurotechnology. Access the <i>event page</i> .
November 2021	OECD-Council of Europe Roundtable (virtual) "Neurotechnologies and human rights framework". Recordings available on the <i>event page</i> .
December 2021	Panel at BNCT/CSTP Conference (virtual) "Harnessing Neurotechnology for Brain Health". Read the conference proceedings.
July 2022	OECD-BrainMind workshop (in-person) "Neuroethics implementation in the private sector". Further information on the <i>event page</i> .
July 2022	Neuroethics roundtable at Federation of European Neuroscience Societies, Neuroscience conference in Paris, France.
October 2023	Workshop "Practical Tools for Responsible Neuroinnovation" with companies and investors at BrainMind Summit in San Francisco, US. Further information on the <i>summit page</i> .

Discover the navigation of this Toolkit

Explore the implementation goals

Read more on the OECD Neurotechnology Recommendation

NAVIGATING THIS TOOLKIT

This Neurotechnology Toolkit is organised into 13 thematic goals. These goals are grouped in five elements:



These five elements are the building blocks of the **OECD Framework for Anticipatory Governance of Emerging Technologies**. It focuses on anticipatory concepts and tools which might guide the trajectory of emerging technologies and aims to equip governments, other innovation actors and societies more broadly to:

leverage emerging neurotechnologies for societal benefit;

better anticipate, prepare for and act on governance challenges in future emerging technology contexts; and

build longer-term governance capacities to deal with emerging technologies more effectively and efficiently.

As such, the framework offers a unifying approach to the governance of emerging technologies. Building on existing OECD standards, tools, and good practices, it is meant to engage upstream and at different stages of the innovation process.

Explore the implementation goals

Learn more about the Recommendation's history and implementation

Read the Framework policy paper publication

Guiding Values Strategic Intelligence and Oversight Stakeholder Engagement **Agile Regulation**





Neurotechnology development should be anchored in guiding values to ensure that neurotechnology governance aligns with human rights, democratic principles, sustainability, equity, inclusion, safety and the public good. Ethical, social and political dialogue can nurture and develop this values-based innovation culture. Integrating these values throughout the entire process, from agenda-setting to deployment by innovators, is vital to ensuring responsible and inclusive technological advancement.



INNOVATING FOR THE PUBLIC GOOD



ENSURING SAFETY AND SECURITY



ENSURING INCLUSION AND ACCESS



PROTECTING DATA PRIVACY



ENSURING COGNITIVE LIBERTY

Strategic Intelligence and Oversight



Stakeholder Engagement



Agile Regulation









Strategic Intelligence and Oversight

Recognising the unpredictable nature of emerging technologies, policies should foster shared forms of strategic intelligence, involving the comprehensive analysis of technology's potential directions, economic stakes and societal implications. Robust tools like horizon scanning, advanced data analytics, forecasting and technology assessment should be employed to anticipate future challenges and inform governance strategies. This anticipatory approach could help inform the development of strategic visions, plans and roadmaps for neurotechnologies.



ANTICIPATING TECHNOLOGICAL CHANGE AND IMPACTS



EQUIPPING INSTITUTIONAL OVERSIGHT

Stakeholder Engagement



Agile Regulation







Strategic Intelligence and Oversight





Stakeholder Engagement

Policies should prioritise the proactive engagement of stakeholders and the broader society in the policy-making process for emerging neurotechnologies. Similarly, engaging diverse actors early in the technology development cycle enriches the understanding of issues, fosters trust and aligns technological innovation with societal needs. Tools for societal engagement, including capacity-building, communication, consultation and co-creation, should be leveraged to ensure diverse participation and alignment of science and co-design of neurotechnology strategies and governance.



CONSULTING AND COMMUNICATING WITH CITIZENS



ENABLING INCLUSIVE DECISION-MAKING AND TECHNOLOGY DEVELOPMENT

Agile Regulation







Strategic Intelligence and Oversight



Stakeholder Engagement





Agile Regulation

Given the fast pace and evolving nature of emerging neurotechnologies, governance systems should strive for agility and anticipation through adapting regulatory tools, fostering inter-agency cooperation, developing forward-looking governance frameworks and ensuring responsiveness to stakeholder concerns. Experimentation and testing under regulatory supervision e.g. testbeds, sandboxes, should be encouraged to foster innovation, reduce uncertainty and ensure that governance systems remain relevant and effective. Private sector forms of governance can be an important part of the ecosystem of approaches.



RESPONSIVE GOVERNANCE AND REGULATORY ADAPTATION



ENCOURAGING RESPONSIBLE BUSINESS





Strategic Intelligence and Oversight



Stakeholder Engagement



Agile Regulation



International Cooperation



Acknowledging the transboundary nature of neurotechnology, policies should promote international cooperation in the face of a fast-moving technological development and a shifting geopolitical landscape. Scientific cooperation can derive from both technological advances and the harmonisation of norms. Forward-looking dialogue in inclusive forums should be facilitated to coordinate approaches to emerging technology governance, share experiences, deepen understandings and lay the groundwork for collective standard-setting. Promoting a multistakeholder, consensus-driven development of standards and principles ensures the interoperability of emerging technologies and the creation of markets for responsible technology products and services.



COLLABORATIVE RESEARCH AND DEVELOPMENT



DEVELOPING INTERNATIONAL STANDARDS



INNOVATING FOR THE PUBLIC GOOD

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Funders, including government agencies and private foundations, could prioritise grants and awards for neurotechnology projects that are aligned with human health and flourishing and developed through inclusive processes.

Policymakers could ensure that strategies and roadmaps for neurotechnology research and development promote responsible innovation. Such projects would:

Demonstrate a strong commitment to responsible innovation, including respect for the autonomy, safety, and data privacy of individuals.

Show potential for significant positive impact on human health and well-being, particularly focusing on underserved areas of neurological and mental health and disease.

Engage in proactive public and stakeholder engagement throughout the development process, from design to deployment. <u>See "Stakeholder Engagement"</u>

Promote collaboration across sectors and jurisdictions. <u>See</u> "<u>International Cooperation</u>"

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 1 a | c | d

Principle 2 a



INNOVATING FOR THE PUBLIC GOOD

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Charter for the responsible development of neurotechnologies, France

In 2022, the French Ministry of Higher Education and Research adopted a national Charter for the Responsible
Development of Neurotechnologies. It
outlines measures to protect patients and
consumers against the potentially harmful applications of neurotechnologies for both medical and non-medical purposes. The charter was jointly elaborated by all its stakeholders government, industry, academia, patient associations as well as France's Comité Consultatif National d'Ethique (CCNE) - and its wording results from collegial exchanges between public and private actors. In March 2024, the Charter had 34 signatories from the public and private sector in France. Read the Charter in French and in English.



Implementing ethics into brain research, EU

From 2013 to 2023, the EU's Human Brain Project (HBP) brought together stakeholders from across the EU to conduct research on various aspects of neuroscience and neurotechnologies. To ensure the integration of ethical and ensure the integration of ethical and professional standards throughout the projects' activities, the HBP established the Ethics & Society group, which worked to embed ethics and philosophy into its 10-year tenure. This involved developing training resources and toolkits to strengthen responsible research and innovation capacities within the HBP and innovation capacities within the HBP and EBRAINS, an international research infrastructure that the HBP left as its legacy. Learn more about Ethics & Society at the HBP and EBRAINS

Ministerial Declaration for the advancement of human rights in neurotechnologies, EU

In 2023, Ministers from the European Union adopted the León Declaration on European neurotechnology, affirming their willingness to protect human and digital rights in the development of neurotechnologies. This involves encouraging public-private cooperation, fostering a diverse and inclusive ecosystem, providing incubators for the development of EU-based technologies, varieing a was proposed for this all dispersions. raising awareness of ethical dimensions among developers, informing and involving the public and collaborating with standard-setting bodies to further develop best practices in the field. Learn more.

Neuroscience research prize, Norway

Established in 2005, the Kavli Prize is awarded every even-numbered year in three fields – astrophysics, nanoscience and neuroscience. The Kavli Prize in Neuroscience is awarded for outstanding achievement in advancing knowledge and understanding of the brain and nervous system. This initiative is a partnership between The Norwegian . Academy of Science and Letters, The Norwegian Ministry of Education and Research, and The Kavli Foundation (US). Learn more

Support for socially responsible technology, Ireland

Since 2018, the Future Innovator Prize has supported interdisciplinary teams in developing technologies to address societal challenges on both a national and international scale. A challenge-based programme, it aims to promote technology for social good by providing funding to those engaging with diverse stakeholders to develop solutions with high capacity for impact. Learn more.







ENSURING SAFETY AND SECURITY

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers and/or regulators could encourage a "safety by design" approach to neurotechnology development and post-market oversight. Such an approach could incorporate phased safety assessments, including cybersecurity risks and national security considerations to allow pre-market and post-market mitigation of risks. This approach could encourage researchers, developers, IRBs/ERBs¹ and manufacturers to:

Conduct and disclose results of "red teaming"² exercises to identify and mitigate unforeseen risks to individuals and society, including vulnerabilities that could be exploited for unauthorised data access or system manipulation and dual-risk possibilities.

Develop and implement dynamic scenario planning for early detection and mitigation of safety and ethical concerns, including dual-risk concerns, to focus attention on import/export controls of component parts of neurotechnology devices. <u>See "Anticipating Technological Change and Impacts"</u>

Empower IRBs/ERBs to evaluate neurotechnology research proposals for ethical, safety and cybersecurity implications, focusing on comprehensive risk assessment and participants' data privacy and cognitive liberty. <u>See "Protecting Data Privacy"</u> <u>See "Ensuring Cognitive Liberty"</u>

Engage with multi-disciplinary pre-market and post-market safety audit teams, including ethicists, user representatives, cybersecurity experts and national security advisors throughout the development process and post-market launch to ensure a holistic view of safety and oversight. See "Enabling Inclusive Decision-Making and Technology Development"

Incorporate considerations of both individual and societal risks, as well as of strategic implications of technology proliferation. <u>See "Responsive Governance and Regulatory Adaptation"</u>

Introduce incident-based and post-market surveillance programs to collect and scan for incidents of safety in consumer products. When innovations are applied to patients, consider the use of Critical Incident Reporting Systems (CIRS), ideally open to patient input.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 2 c | d

¹ An institutional review board (IRB), also known as an ethics review board (ERB), is a committee that reviews proposed research projects involving human subjects to ensure the active consideration and application of ethical values throughout.

² Red teaming occurs when hackers are authorized by your organization to emulate real attackers' tactics, techniques and procedures (TTPs) against your own systems.



ENSURING SAFETY AND SECURITY

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Regulation of medical devices, Canada, US, EU:

In many OECD jurisdictions, regulations outline strict requirements for medical devices to be safe, effective, and of high quality. Only those demonstrated to have benefits that outweigh their risks can be authorised for sale. Examples include the Medical Devices Regulations section of Canada's Food and Drugs Act (F&DA); the US Medical Devices Regulation by the Food and Drug Administration (FDA); and the EU's Medical Devices Regulation (MDR)



dual use, EU

From 2013 to 2023, the EU Human Brain Project (HBP) operated a **Dual Use** Working Group which examined potential risks arising from emerging technologies with multiple applications, notably those which may be used in the political, security, intelligence and military (PSIM) domains, and issued an opinion proposing recommendations for their safe development and regulation. Learn more.

Research into ethical dimensions of dual use technologies for security, Germany

The Joint Committee on the Handling of Security-Relevant Research, established by the German National Academy of Sciences, Leopoldina, and the German Research Foundation (DFG), works to raise awareness among researchers of dualuse issues in security-relevant research. It aims to promote a responsible approach to future research on the subject and ensure self-governance within the scientific community. Leopoldina and the DFG also assisted in the formation of independent Committees for Ethics in Security-Relevant Research across German research institutions to provide guidance on security-relevant research which may be incorporated to meet eligibility criteria for government funding. Learn more about the *Joint Committee on* the Handling of Security-Relevant Research and the independent committees

Review of digital technologies for health, Canada

In 2018, Health Canada created a new Digital Health Division to increase its capacity for regulating existing and emerging digital health technologies, including medical software, artificial intelligence and wearable devices, and to develop policies for medical device cybersecurity in order to protect citizens from security breaches. Learn more.







ENSURING INCLUSION AND ACCESS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Funders, including government agencies and private foundations, could prioritise development of and access to neurotechnologies for marginalised communities by:

Supporting projects that adapt existing technologies for low-resource settings and research into affordable innovations.

Setting aside a portion of existing health and technology research budgets specifically for inclusivity-focused projects.

Ensuring project applications explicitly address inclusion criteria and demonstrate engagement with target communities. <u>See "Inclusive decision-making"</u>

Requiring IRBs and ERBs to adopt inclusivity criteria as part of their review process for approving clinical trials, and providing specific guidelines for equitable participant recruitment and diverse demographic representation.

Engaging vulnerable groups (like neurodivergent individuals, disabled persons and patient groups) when developing funding priorities to ensure that their perspectives are included and prioritised.

Developing reimbursement plans for neurotechnology products or services created in accordance with diversity and inclusivity standards.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 3 a | b | c



ENSURING INCLUSION AND ACCESS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER



Inclusive multidisciplinary neurotechnology community, UK

The network RESPECT 4
Neurodevelopment seeks to promote responsible, reliable, scalable and personalised neurotechnologies specifically for infants and children with neurodevelopmental conditions by bringing together a wide range of stakeholders, including patients and their family members, and ensuring that their priorities and concerns are considered. In doing so, it works to integrate multiple perspectives throughout the neurotechnology lifecycle and promote the development of accessible and effective neurotechnology devices.

Learn more.



The Tri-Agency Strengthening Indigenous Research Capacity Strategic Plan (2020-2026) was launched in response to the Canadian Government's commitment to develop a better relationship with Indigenous Peoples. The Plan aims to identify new ways for Indigenous groups to conduct research and engage with the broader scientific community by supporting Indigenous research priorities, improving access to funding and ensuring leadership and self-determination of Indigenous persons throughout the research process.

Learn more.





PROTECTING DATA PRIVACY

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers could review existing hard and soft-law mechanisms, as well as other policy instruments, to evaluate whether they sufficiently protect against novel risks to data privacy. In the event that they do not, policymakers could:

Expand existing biometrics rules to provide more robust protections for individuals for the collection, processing and use of their biometric information to make inferences about their brain activity and/or mental states.

Provide special protections for "neural data": data derived from any biosensor technologies that measure or monitor an individual's physiological, biological, or behavioural activities, which could be used to infer cognitive functions, mental states or psychological patterns, including specific protections to safeguard against discrimination.

Establish robust consent frameworks for the collection, processing, use, and/or sharing of neural data or cognitive biometrics to ensure that consent is informed, specific and revocable.

Encourage industry-wide data-privacy standards for neural data such as edge-storage, edge processing, on-device encryption, anonymisation techniques, data minimisation and use restrictions. <u>See "Developing International Standards"</u>

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 1 d

Principle 7 a | b | c | d | e | f | g



PROTECTING DATA PRIVACY

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER



Bill to protect privacy of biological data, US

In 2021, the Colorado Privacy Act was introduced as part of the Colorado Consumer Protection Act to outline new consumer rights and establish conditions for entities handling personal data. This involved the expansion of the definition of "sensitive data" to include biological data, such as neural data, which relates to the activity of an individual's brain and nervous systems that can be recorded and processed using an external device. Learn more.



Consent forms for the collection of neurological data, Japan

In 2024, Japan's Centre for Information and Neural Networks (CiNet) published **templates for informed consent in their Braindata Guidelines** to provide guidance for the collection of neurodata and its use in the construction of Al models. <u>Learn more</u>.



Bioethics law addresses privacy of brain data, France

Since 2011, the French Bioethics Law requires that the recording and monitoring of brain activity be conducted only for medical purposes, scientific research or in the case of judicial expertise. The 2021 revision of the law stipulates that the use of Functional MRI (fMRI) of the brain is excluded in the case of judicial expertise. Learn about the provisions presented for consideration during the law's revision (2018-2021) and read the revised Bioethics Law.



Laws for the protection of personal data, EU and UK



Applicable as of 2018, the EU's **General Data Protection Regulation (GDPR)** lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data. Personal data refers to any information relating to an identified or identifiable natural person. Although the GDPR does not have any specific provisions relating to brain data, some of the identifiers it mentions (in the definition provided in Article 4.1) include those specific to the physical, physiological, genetic and mental identity of the natural person. In addition, data concerning health qualifies as a special category of personal data under the GDPR. The UK GDPR, which originated from the EU legislation, employs the same definition of personal data. Learn more about the *EU GDPR* and the *UK GDPR*.

Principles for the safe and effective use of data and analytics, New Zealand

In 2018, the Privacy Commissioner and the Government Chief Data Steward of New Zealand collaborated in the **development** of six key principles to support safe and effective analytics of personal data. They are to deliver clear public benefit; ensure data is fit for purpose; focus on people; maintain transparency; understand the limitations; and retain human oversight. Learn more.



ENSURING COGNITIVE LIBERTY¹

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers could review existing hard and soft-law mechanisms to evaluate whether they sufficiently protect against novel risks to cognitive liberty. In the event that they do not, policymakers could:

Update existing laws and/ or adopt new laws, policies or regulations that protect individual rights to self-determination, mental privacy and freedom of thought.

Enhance individual rights to access, correct, and delete their neural data, and to be informed of data breaches in a timely manner. <u>See "Protecting Data Privacy"</u>

Address ethical use of and safeguards against discrimination with neurotechnologies in specific contexts, including, but not limited to, guidelines for use in workplaces, schools, by government and marketing.

Empower privacy commissioners to actively monitor for risks to cognitive liberty by emerging technologies.

Support the development of a "digital citizenship" curriculum to ensure that individuals understand the impact of emerging technologies on their brain and mental experiences. <u>See "Consulting and Communicating with Citizens"</u>

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 1 d | e

Principle 9 b | c | d

¹ Cognitive liberty refers to self-determination over one's brain and mental experiences. For further information, see: Farahany, N. (2023), The Battle for Your Brain: Defending the Right to Think Freely in the Age of Neurotechnology. St. Martin's Press.



ENSURING COGNITIVE LIBERTY

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Bill to protect mental privacy and cognitive liberty, US

In 2023, a bill concerning data privacy relating to neurotechnology was introduced in Minnesota. It establishes the individual's right to mental privacy and cognitive liberty, and prohibits government entities from interfering with their freedom of thought when making neurotechnologyrelated decisions. It also requires companies involved in the gathering and storing of neurological data to take measures to ensure the informed consent of affected individuals. Learn more.



Neurorights bill and desire for institutional reform, Chile

In 2021, Chile passed a **neurorights** protection bill to address specific ethical concerns related to brain data and neurotechnology, such as "mental integrity," "psychic continuity," and "identity". In a landmark ruling in 2023, the country's Supreme Court required the bioinformatics company Emotiv to delete all brain data it had collected from former Senator Guido Girardi. Learn more.

Charter of digital rights, Spain

The Spanish Charter of Digital Rights (2018) includes a section referring to rights under the use of neurotechnologies stating that implantation and deployment of neurotechnologies in humans should, among other things, protect personal identity, guarantee self-determination, and safeguard personal data. Learn more.





ANTICIPATING TECHNOLOGICAL CHANGE AND IMPACTS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

National scientific agencies or institutes could offer targeted funding opportunities and/or promote collaborations between academia, government and industry to support national and international foresight and technology assessment initiatives on neurotechnology. These efforts could:

Fund interdisciplinary teams for ongoing assessment of neurotechnologies, emphasising ethical, legal, social, and technological perspectives.

Promote the use of a robust portfolio of tools including horizon scanning, advanced data analytics, forecasting and technology assessment to increase forward-looking intelligence.

Develop and implement scenario planning, using data-driven approaches, to identify potential developments and likely impacts of neurotechnologies.

Include diverse communities and experts in foresight and other forward-looking exercises. See "Enabling Inclusive Decision-Making and Technology Development"

Create openly accessible cross-agency and international repositories for neurotechnology technology assessments.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 2 b

Principle 6 e

Principle 9 a



ANTICIPATING TECHNOLOGICAL CHANGE AND IMPACTS

EXAMPLES TO CONSIDER



The TechEthos project (2021-2023) identified ethical, political and societal impacts of three emerging technologies: neurotechnologies, climate engineering and digital extended reality. The process included consultations with experts and citizens alike to determine awareness and acceptance of novel technologies, highlight governance gaps and propose solutions for improvement. Reports showcasing findings and a Societal Readiness Tool (SRT), which enables users to assess the potential impact and readiness level of their products, can be found on the TechEthos website. Learn more about their work on neurotechnologies and the latest draft of the SRT.



In 2024, the World Economic Forum launched an interactive Transformation Map that presents foresight analysis of various social implications of neurotechnologies, both individually and in convergence with other emerging tech, and proposes recommendations for relevant actors to mitigate potential harms. This is one of multiple horizon scans included in the World Economic Forum's work on strategic intelligence which aims to highlight expert insights and predictions on those issues with high potential for future impact. Explore the neurotechnology transformation map and discover *horizon scans for other* technologies.



Multistakeholder inputs inform BCI roadmap, EU

The BNCI project (2015-2025) is developing a roadmap outlining future applications, impacts and challenges of braincomputer interface (BCI) technologies by fostering collaboration and communication among stakeholders including research groups, companies, end users, policy makers, and the general public. It sets out to identify and provide recommendations for the responsible and sustainable funding and development of BCI technologies. Learn more.



The German Federal Ministry of Education and Research (BMBF) supports and funds research on the ethical, legal and social and other non-technical impacts of new technologies to assess the opportunities and risks as early as possible. These results facilitate societal discourse, raise awareness among researchers, developers, users and the general public, and guide political decision-making. This enables the participation of all relevant actors, promotes responsible research and ethical technology design, and supports the transition into application. <u>Learn more</u> (in German).





EQUIPPING INSTITUTIONAL OVERSIGHT

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers and human subject research institutions could take measures to ensure that institutional oversight has the capacity to anticipate and address emerging governance issues. These efforts could:

Establish cross-sectoral working groups to identify gaps, explore solutions to governance needs for rapidly developing neurotechnologies and coordinate policies across agencies and institutions to ensure their alignment.

Publish ongoing recommendations and guidance for neurotechnology activities based on rigorous research and stakeholder engagement. <u>See "Stakeholder engagement"</u>

Support training and education of individuals, including neurotechnology researchers, grant recipients, IRBs/ERBs and those at various levels of government who review and approve the use or marketing of technologies to develop the requisite expertise for evaluating new ethical implications and/or governance of emerging neurotechnologies.

Sponsor structured exchanges between regulators, academics, innovators and citizen groups to co-develop flexible and effective oversight mechanisms. <u>See "Responsible Governance and Regulation"</u>

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 6 b | d

Principle 8 d



EQUIPPING INSTITUTIONAL OVERSIGHT

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Science and technology assessment, US

The Government Accountability Office (GAO) conducts a wide variety of technology assessments which evaluate the application of emerging and evolving technologies in government, examine their impact on society and provide the Congress and public with strategic intelligence to inform their use. Their published work includes information on neurotechnology (specifically BCIs and cognitive assessment apps), their many opportunities, and the safety, ethical, and regulatory concerns associated with their use. Full technology assessments and shorter Science and Technology (S&T) spotlights are publicly available online. Learn more about the GAO's assessments and read the spotlight on BCIs.

Technology assessment committee in a major health funding agency, US

The Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) at the US NIH is a federal advisory committee that provides recommendations to the NIH Director and serves as a public forum for discussions on the scientific, safety, and ethical issues associated with emerging biotechnologies. To enhance accessibility, proceedings and reports are publicly available online. Learn more.

Independent agency for participatory technology assessment, the Netherlands

The Rathenau Institute in the Netherlands conducts research projects on the ethical, political and social impacts of science, technology and innovation. To elicit public values, it involves a variety of stakeholders ranging from scientific and technological experts to members of the broader society and produces reports to guide parliamentary decisions. Learn more.

Parliament advisory body on scientific and technological change, Germany

The Office of Technology Assessment at the German Bundestag (TAB) is an independent scientific institution and advisory body for the parliament. Its tasks include the observation and analysis of important scientific and technological trends and related societal developments to inform decision-making and public dialogue on technological developments and innovations. Learn more.

National ethics committee, France

The French Comité Consultatif National d'Ethique (CCNE) explores questions relating to health and society raised by scientific advancements, and shares findings with decision-makers and the public to inform debates on ethical issues. It also publishes notes and reports for the French government, such as Opinion 129, which guided the revision of the French Bioethics Law (2011-814) in 2018. Since 2011, this law includes two sections on neurotechnologies. Learn more about the CCNE and read a summary of Opinion 129 (in English).

National ethics council, Germany

The German Ethics Council addresses questions of ethics, society, science, medicine, law and the potential consequences for the individual and society that arise from research and development, especially in the area of life sciences and their application to humans. Its duties include informing the public, encouraging discussion in society and preparing opinions and recommendations for political and legislative actors. Learn more.





Stakeholder Engagement

CONSULTING AND COMMUNICATING WITH CITIZENS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers and funders could provide targeted support to public health organizations, researchers, and educational institutions to develop educational materials and campaigns that:

Foster neurotechnology education by integrating relevant information into broader health, science, and technology curricula.

Train scientists and technical experts to communicate with broad audiences in a balanced way that avoids hype and counters misinformation from deceptive marketing practices.

Through partnerships with industry and research institutions, create interactive learning experiences, such as public demonstrations, webinars, and open days to demystify neurotechnologies and promote informed public discourse.

Support diverse mechanisms to solicit citizen viewpoints and promote diverse interactions between experts and non-experts, e.g., focus groups, citizen juries, citizen assemblies and dialogues, science museum exhibits, science cafés and artist-in-residence programmes.

Develop communication platforms and channels to share with the public key insights from formal dialogues and debates on the risks and benefits of emerging neurotechnology applications as well as the latest information on their advances.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 5 a

Principle 8 c



Stakeholder Engagement

CONSULTING AND COMMUNICATING WITH CITIZENS

EXAMPLES TO CONSIDER

National bioethics consultation, France

The revision of the French Bioethics Law (which dates from 1994, with new versions in 2004 and 2011) is a process which requires involving the public in debates and consultations. A National Bioethics Consultation in 2018 identified avenues for the revision of the law and informed Opinion 129 by France's Comité Consultatif National d'Éthique (CCNE), which provided an overview of the topics presented for debate. Learn more about the public consultation and read a summary of Opinion 129 (in English).



Neuroethics Principles to promote multistakeholder dialogue, US

In 2018, the BRAIN 2.0 Neuroethics Subgroup (BNS) released their **Neuroethics Guiding** Principles as a means of promoting dialogue about responsible neuroscience research and development between different stakeholders. In addition to regulation, the BNS highlights the importance of multistakeholder dialogues in effectively addressing the ethical, legal and social implications of neuroscience. Learn more.



Programme for public communication of sciences, Portugal

Established in 1996, Ciência Viva is a **government programme** which promotes communication of scientific knowledge and culture with the public. By cultivating alliances between various facets of Portuguese society, it aims to facilitate the development of a cross-disciplinary network which fosters dialogue with students and professionals of all ages across Portugal and Europe alike. Learn more.



Public art exhibition on the brain, Germany

Berlin's Museum of Medical History of the Charité is hosting the **exhibition "The Brain in Science and Art"** (2023-2024) to educate the



general public on the brain's anatomy, its features and their associated functions, including perception, sensation, memory and thought. At the same time, it raises questions about the ego and the self and its relationship with the external world to encourage the viewer to engage with the brain from a variety of angles. Learn more.

Multistakeholder neurotechnology research expo, UK



In 2024, N-CODE, a multistakeholder network in the field of neurotechnology, is hosting a cross-disciplinary expo to convene relevant actors in examining the latest research and innovation on the subject. In doing so, it aims to advance technologies that facilitate communitybased diagnosis and treatment of neurological conditions. Learn more.

International public awareness campaign on brain research



Brain Awareness Week is the global campaign to raise awareness of positive developments in brain research and foster public support for **neuroscience**. Many national initiatives also take place during this time, like the Week of the Brain in Czechia, during which public events are organised to shed light on the newest discoveries and trends in the field. Learn more about Brain Awareness Week and Czechia's Week of the Brain.

Societal engagement on neuroenhancement technologies, EU



The European Commission's Neuro-Enhancement: Responsible Research and Innovation (NERRI) project (2013-16) set out to influence the normative structure underlying the governance of neuro-enhancement (NE) technologies. This was achieved through engaging stakeholders from science, policy, industry, civil society and the general public in discussions about the ethical, social, legal and economic aspects of NE technologies. Learn



ENABLING INCLUSIVE DECISION-MAKING AND TECHNOLOGY DEVELOPMENT

POSSIBLE ACTIONS

FXAMPLES TO CONSIDER

Policymakers and industry leaders could collaborate on the development and deployment of a structured multi-stakeholder engagement process to ensure that diverse inputs are considered in neurotechnology development and governance. This could include:

Forming advisory panels that include representatives from underrepresented communities, ethicists, patient advocacy groups, neurotechnology users and other stakeholders to participate in decision-making processes for neurotechnology initiatives.

Hosting regular public consultations and forums to gather input on neurotechnology development projects and policy proposals.

Supporting initiatives that combine policy co-design, interdisciplinary research, and collaborative platforms like living labs to ensure that neurotechnologies are co-created through active participation of diverse stakeholders, integrating insights across science, technology and society.

Implementing formal feedback loops and accountability measures for decision-makers to ensure that the input from these dialogues are actively considered in policy development, research funding decisions and the design of neurotechnologies.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 1 b

Principle 5 b | c | d



Stakeholder Engagement

ENABLING INCLUSIVE DECISION-MAKING AND TECHNOLOGY DEVELOPMENT

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER



Public engagement project, EU

During the final stage of its 2013-2023 tenure, the EU Human Brain Project (HBP) engaged citizens and stakeholders in discussions on ethics, gender and diversity, foresight and public deliberation in its Responsible Research and Innovation (RRI) work package (formerly known as Ethics and Society). This was conducted in collaboration with the Danish Board of Technology (DBT), as was the Inclusive Community Building project, which aimed to develop an international research network and foster collaboration across scientific disciplines. Learn more.



Network for chronic pain neurotechnology, UK

Launched in 2022, the UK's Chronic Pain
Neurotechnology Network+ aims to build a
UK-wide ecosystem dedicated to enhancing
the effectiveness of neurotechnology for
chronic pain. With participation from
researchers, clinicians and patients, the
community explores current developments and
their associated opportunities and challenges,
conducts research to enable future
advancements in the field, and builds
infrastructure to support further collaborative
and multidisciplinary work of a similar nature.
Learn more.



Brain research impact framework, EU

From 2018 to 2020, the Multi-Act project worked to foster collaborations amongst patients, patient organisations, academics and private and public stakeholders to diversify perspectives in and increase the impact of brain research. This involved creating a governance model outlining five criteria to improve cooperation and efficacy in both agenda-setting and evaluation of research results. *Learn more*.



Neurotechnology engagement network, US

The US Neurotech Network is a non-profit organization working to engage neurotechnology patients and end-users in the development of neurotechnology devices. It aims to ensure the inclusion of user preferences and experiences to improve future access to neurotechnology products. It also offers a range of community engagement services and resources to encourage further discussion between developers and their target patients. Learn more about *their mission* and discover *their engagement services*.



Multistakeholder research network for neural interface technologies, UK

The Closed-loop Neural Interface Technologies (CloseNIT) Network+ brings together stakeholders from academia, industry and medicine to examine the opportunities and challenges arising from closed-loop neural interfaces. The network organises conferences, research exchanges, patient and public dialogues and research projects to ensure the inclusion of a wide range of perspectives throughout the research process. Learn more.



Collaborative community to drive responsible neurotechnology innovation, US

In 2024, the Implantable Brain-Computer Interface Collaborative Community (iBCI-CC) was established to drive continuous innovation and equitable access to implantable BCIs. It convenes diverse stakeholders ranging from industry actors, developers, people with lived experience and regulators to facilitate meaningful engagement regarding BCIs and promote equitable access to such technologies once they reach the market. In particular, it leverages multistakeholder discussions to identify clinical, regulatory, coverage and payment questions hindering patient access to neurotechnologies, and provides a platform to address such impediments. Learn more.





RESPONSIVE GOVERNANCE AND REGULATORY ADAPTATION

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers could review existing hard and soft-law mechanisms to enable agile governance as technologies evolve and consider:

Whether to adopt a tiered or risk-based approach to governing neurotechnologies based on their potential impact on safety, privacy, and cognitive liberty. *See "Ensuring Safety and Security"*

Developing and/or implementing a pre-market impact assessment requirement prior to marketing for public use. <u>See "Developing International Standards"</u>

Supporting the use of regulatory sandboxes and/or test beds to monitor real-world applications of neurotechnologies.

Adopting non-binding guidelines that can be quickly updated in response to new neurotechnology developments and insights.

Using upstream governance approaches that build values into the development of neurotechnologies using "ethics-by-design" or "privacy-by-design" approaches.

Extending existing regulation to cover the full lifecycle of neurotechnology solutions, ensuring that patients and consumers can receive guaranteed support for as long as needed (e.g., for the duration of benefiting from brain stimulation through an implant).

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 1 f Principle 8 b Principle 6 a



RESPONSIVE GOVERNANCE AND REGULATORY ADAPTATION

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Identifying regulatory pathways for medical devices to enter the market, US

Since 2012, the US Food and Drug Administration (FDA) has run a presubmission programme that facilitates collaboration between innovators and FDA staff to determine efficient and appropriate regulatory pathways through which to bring medical devices to the US market. This includes a regulatory review of neurological devices. In 2021, the FDA also developed guidance on implanted brain-computer interfaces (BCI) for patients with paralysis or amputation. Learn more about the pre-submission programme and the guidance on BCI.

Global monitoring of legislative developments, Korea

The Global Legislative Strategy team at the Korea Legislation Research Institute (KLRI) monitors new legal changes abroad. In 2020, it published a paper regarding issues and implications of the OECD Recommendation on Responsible Innovation in Neurotechnology in the KLRI brief. Learn more about *the KLRI* (in Korean). Read *the paper* (in Korean).

Sandbox to develop emerging technologies, Malta

Malta's **Technology Assurance Sandbox** aims to provide a safe environment for the development of technological solutions in line with recognised standards. It provides a suitable **environment for companies to develop, deploy and test solutions for emerging technologies** like blockchain and artificial intelligence, and amend them to ensure alignment with existing regulations. *Learn more*.

Framework to address human rights concerns in facial recognition technology, France

Since 2019, France's Digital Council has collaborated with the World Economic Forum to develop a policy framework addressing human rights concerns arising from the use of facial recognition technology. The framework is intended to outline principles that define responsible use, develop approaches to integrate responsibility into design from the outset, assess relevance and applicability of such methodologies and audit adherence to the principles over time. Learn more.





ENCOURAGING RESPONSIBLE BUSINESS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers, government agencies, and funders could incentivise, through policies and funding opportunities, industry-wide initiatives to develop common ethical and transparent practices in research, development, deployment and oversight of neurotechnologies. This could include support for:

Industry leaders to launch industry-wide initiatives to develop common ethical and transparent practices in the development and deployment of neurotechnologies.

Funding and ongoing support to develop and maintain a centralised online portal for public access to research data, safety assessments, ongoing clinical trials and technological developments. See "Collaborative Research and Development"

Facilitating ongoing public input through structured stakeholder dialogues to inform development and governance. <u>See "Enabling Inclusive Decision-Making and Technology Development"</u>

Establishing policies in technology transfer offices of research institutions to ensure that neurotechnology IP developed with public funds is licensed so as to align with ethical standards and foster equitable access.

Ensure transparent reporting of ethical considerations and potential conflicts of interest in all stages of neurotechnology development.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 5 e Principle 8 a | e Principle 6 c



Agile Regulation

ENCOURAGING RESPONSIBLE BUSINESS

EXAMPLES TO CONSIDER





In 2022, the OECD, in collaboration with BrainMind, organised an interdisciplinary meeting to convene various stakeholders to discuss the integration of neuroethics frameworks, including the OECD Recommendation on Responsible Innovation in Neurotechnology, in academia, entrepreneurship, public policy and investment activities. Learn more.

through responsible technology funding, **Norway**

Addressing societal challenges

The Research Council of Norway provides funding to organisations, companies and public sector entities working to develop responsible technology to address societal challenges. It has various "portfolios" which invest in research in areas like health, enabling technologies and social welfare, and provide targeted guidance on innovation in these areas. <u>Learn more</u>.





Conference on neurotechnology innovation, UK

In 2024, Innovate UK's, Knowledge Transfer Network (KTN), organised a conference to convene developers and other relevant stakeholders in the neurotechnology field to examine technological advancements in a variety of areas, including health, entertainment and national security. Learn more.





Introduced in 2000, Canada's Personal Information Protection and Electronic Documents Act (PIPEDA) applies to private organisations in Canada that collect, use or share personal information for commercial purposes. Those that comply agree to obtain an individual's informed consent prior to gathering their data, which may only be used for the purposes for which it was collected. If it is to be used for a reason other than that specified by the organisation, consent must be acquired again. Read PIPEDA in brief and the full legal text.





International Cooperation

COLLABORATIVE RESEARCH AND DEVELOPMENT

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers, government agencies, and funders could incentivize, through policies and funding opportunities, industry-wide initiatives to develop common ethical and transparent practices in research, development, deployment, and oversight of neurotechnologies. This could include support for:

Establishing digital platforms for the global neurotechnology community to share research data, methodologies and findings openly to encourage transparency, reproducibility and collaborative analysis.

Building cross-disciplinary opportunities for collaborations bridging neuroscience, social sciences, humanities and ethical studies.

Sponsoring pre-competitive international consortia involving public research institutions, private sector entities, non-profits and patient advocacy groups.

Supporting cross-border research projects and exchanges among researchers, practitioners and policymakers.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 4 a | b | d



International Cooperation

COLLABORATIVE RESEARCH AND DEVELOPMENT

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

National data-sharing platform, US

OpenNeuro is a free and open platform for validating and sharing brain data (including MRI, PET, MEG, EEG and iEEG) funded by the NIH BRAIN Initiative. It developed a neuroimaging data formatting standard called Brain Imaging Data Structure (BIDS) which serves as a template for the organisation and display of neuroimaging and behavioural data. Learn more.



Multistakeholder community building, Korea

Established in 2011, the Korea Brain Research Institute (KBRI) is a research institution in convergence brain science supported by the Korean government. To foster collaboration and exchange, it organises joint research projects, facilitates resource sharing and hosts student exchange programmes nationally and internationally. In 2016, it formed the Korea Brain Initiative, a 10-year plan aiming to advance brain research through strengthening the neuroscience ecosystem via local, national and global networks. Learn more about the <u>KBRI's</u> <u>mission</u> and <u>the Korea Brain Initiative</u>.



Research hub on the ethical, legal and social aspects of neuroscience, Germany

In 2024, the Neuroethics Research Hub (RHUNE) started operating with funding from the German Federal Ministry of Education and Research (BMBF). RHUNE is an independent structure that will facilitate interdisciplinary exchanges between researchers, promote young talents and build up networks among researchers, industry and politics. As a central national infrastructure, it aims to support and strengthen responsible research in neuroethics and neuroscience. Learn more (in German).



neuroscience research network

The Network of European Funding for Neuroscience Research (NEURON) is part of the European Research Area Networks (ERA-NETs) which are international research projects funded by the European Commission in various fields. The ERA-NET **NEURON** is a co-funded action focusing on the human brain and its diseases. Established in 2003 and currently in its fourth term for the period 2021-2025, it comprises almost 40 ministries and funding agencies from about 28 countries across the EU and beyond, including Canada and Australia. <u>Learn more</u>.



Open digital ecosystem for neuroscience research, EU

An open research infrastructure that gathers data, tools and computing facilities for brain-related research, "EBRAINS" acts a centralised hub convening national research institutes across Europe. Since its inception in 2019, it has provided an accessible online platform facilitating collaborative brain research between organisations and researchers working in various fields of neuroscience. Learn more.

International Brain Initiative



Founded in 2017, the International Brain Initiative (IBI) is a coalition of major brain initiatives from seven nations that convenes stakeholders from academia, the private sector and government to leverage global neuroscience knowledge and resources. To achieve this, the IBI has developed infrastructures and entities that enable international and cross-disciplinary collaboration for research, education and outreach. The IBI also organises events such as workshops, forums and panel discussions, and publishes key reports on its website. Learn more.

Neurotech example



DEVELOPING INTERNATIONAL STANDARDS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER

Policymakers, government agencies and funders could encourage and incentivise, through policies and funding opportunities, international initiatives across the public and private sectors to develop standards to govern neurotechnology innovation.

These activities could promote:

Ethical data practices. <u>see "Protecting Data Privacy"</u> <u>see "Ensuring Cognitive Liberty"</u>

Public disclosure of research findings. See "Ensuring Safety and Security"

Safety "red teaming" processes, disclosures, and mitigation strategies. <u>See "Responsible Governance and Regulatory Adaptation"</u>

Regular engagement with stakeholders through open forums and discussions. See "Enabling Inclusive Decision-Making and Technology Development"

In order to accomplish this, actors might consider:

Events such as workshops, conferences and summits to facilitate the circulation of solutions and practices that promote accountability, transparency and trustworthiness between neurotechnology providers and users.

Standardised ethics and privacy impact assessments to be undertaken pre-and post-market detailing potential risks and respective mitigation strategies.

Participating in international forua and working groups to harmonise emerging neurotechnology governance with existing regulatory standards and practices worldwide.

RELEVANT PRINCIPLES FROM THE OECD RECOMMENDATION

Principle 4 c

Principle 8 a



International Cooperation

DEVELOPING INTERNATIONAL STANDARDS

POSSIBLE ACTIONS

EXAMPLES TO CONSIDER





This policy guidance is an implementation resource of the first international standard in the field. Adopted in 2019, the OECD Recommendation on Responsible Innovation in Neurotechnology consists of nine principles to guide relevant actors in identifying and addressing the ethical challenges of neurotechnology while furthering its responsible development. Learn more.





Roadmap for neurotechnologies and brain-machine interfacing

The IEEE Standards Association launched a project to identify gaps in existing standards for brain-machine interfacing (BMI)/ brain-computer interfaces (BCI) and assembled a roadmap showcasing its findings and establishing priorities for future considerations in this regard. <u>Learn more</u>.



International data standards for neuroscience

Neurodata Without Borders was launched in 2014 as a **mechanism to standardise the sharing, archiving and use of neurophysiology and neuroscience data**. Alongside providing guidance, it acts as a repository for data from neurophysiology experiments, tracking data and stimulus data. *Learn more*.





Founded in 1991, the European Group on Ethics in Science and New Technologies (EGE) is an independent, multi-disciplinary body, which provides the European Commission with policy advice where ethical, societal and fundamental rights issues intersect with the development of science and new technologies. It has established a working group on ethics and governance of neurotechnologies, which was also invited in 2023 to collaborate with international partners to collaborate with international partners to develop a European charter on the responsible development of neurotechnologies.

OECD principles for trustworthy and human-centred AI

In 2019 the OECD launched its AI Principles and corresponding policy recommendations to promote the development and deployment of safe AI and highlight the importance of transparency, accountability and safety. Learn more.



OECD RECOMMENDATION ON RESPONSIBLE INNOVATION IN NEUROTECHNOLOGY ORIGINAL FULL TEXT

Principle 1: Promote responsible innovation in neurotechnology to address health challenges.

To this end, relevant actors should:

a) First and foremost, promote beneficial applications of neurotechnology for health and foster research and development to further this aim.

C4 Innovating for the public good

- b) Integrate ethical considerations and take into account public values and concerns at the planning stage and design phase of technological development.
 - **G** Enabling inclusive decision-making and technology development
- c) Foster alignment of public support and economic incentives for neurotechnology innovation with the greatest health needs.
 - **C4** Innovating for the public good
- d) Avoid harm and show due regard for human rights and societal values, especially privacy, cognitive liberty and autonomy of individuals.
 - **C4** <u>Innovating for the public good</u>
 - **C4** Protecting Data Privacy
 - **C4** Ensuring Cognitive Liberty
- e) Prevent neurotechnology innovation that seeks to affect freedom and selfdetermination, particularly where this would foster or exacerbate bias for discrimination or exclusion.
 - **C4** Ensuring Cognitive Liberty
- f) Encourage greater awareness of existing systems of oversight and, where appropriate, evaluate and work towards adapting existing laws and regulations for medical practice and research for application to activities involving neurotechnology.
 - **C4** <u>Responsive governance and regulatory adaptation</u>

Publications and other resources related to Principle 1



Principle 2: Prioritise assessing safety in the development and use of neurotechnology.

To this end, relevant actors should:

a) Engage in communication among researchers, research participants, health professionals, patients, members of the public, private stakeholders and government stakeholders to incorporate concepts of autonomy, harm reduction and safety into research prioritisation processes.

C4 Innovating for the public good

b) Encourage early consideration of potential unforeseen side effects in the research and development of neurotechnologies.

C4 <u>Anticipating technological change and impacts</u>

c) Promote market entrance based on sufficient evidence as to the safety, quality and efficacy of new products and procedures as defined by relevant authorities.

C4 Ensuring safety and security

d) Establish mechanisms for both short-term and long-term oversight, monitoring and reporting of product safety and security, including the implementation of rigorous safety and security standards.

C4 Ensuring safety and security

Publications and other resources related to Principle 2

Principle 3: Promote the inclusivity of neurotechnology for health.

In order to achieve such inclusivity, relevant actors should:

a) Strive to ensure neurotechnology is both developed for and available to those in need.

G Ensuring inclusion and access

b) Promote an enabling policy environment that advances the inclusion of underrepresented populations including, inter alia, social and economic populations, as well as sex- and age-specific groups, in neurotechnology research and development.

C4 Ensuring inclusion and access

c) Take into account the diversity of cultures and strive to minimise inequalities with respect to, inter alia, socio-economic and cultural norms, in the development and use of neurotechnology.

C4 Ensuring inclusion and access

Publications and other resources related to Principle 3



Principle 4: Foster scientific collaboration in neurotechnology innovation across countries, sectors, and disciplines.

In order to achieve this, relevant actors should:

- a) Promote interdisciplinary research and development where communities of scientists and engineers interact closely with the social sciences and humanities communities as well as with user and other relevant groups.
 - **C4** Collaborative research and development
- b) Foster pre-competitive consortia of collaborative research across public research institutions, private non-profit organisations, private sector entities and patient communities.
 - **C4** Collaborative research and development
- c) Support the development of standards and best practices for the technical as well as ethical, legal and social aspects of innovation in neurotechnology.
 - **C4** <u>Developing international standards</u>
- d) Support an international culture of "open science" by creating joint infrastructures and environments for sharing, aggregating, auditing and archiving data relating to neurotechnology as appropriate.
 - **C4** Collaborative research and development

Publications and other resources related to Principle 4

Principle 5: Enable societal deliberation on neurotechnology.

In order to enable such deliberation, relevant actors should:

- a) Promote open communication across expert communities and with the public to promote neurotechnology literacy and the exchange of information and knowledge.
 - **C** Consulting and communicating with citizens
- b) Engage in multi-stakeholder dialogues and deliberation to ensure diverse inputs into decision-making processes, public policy and governance.
 - **G** Enabling inclusive decision-making and technology development
- c) Ensure that the results of formal dialogues are considered and taken into account in decision-making wherever possible.
 - **G** Enabling inclusive decision-making and technology development
- d) Ensure processes for engaging stakeholders are fair, transparent and predictable.
 - **G** Enabling inclusive decision-making and technology development



e) Encourage transparent processes of technology appraisal to deepen and inform public debate about the longer-term trajectory of neurotechnology.

C4 Encouraging responsible business

Publications and other resources related to Principle 5

Principle 6: Enable the capacity of oversight and advisory bodies to address novel issues in neurotechnology.

To this end, relevant actors should:

a) Encourage regulatory agencies, funding bodies, research institutions and/or private actors to respond to opportunities and ethical, legal and social issues raised by advances in brain research and neurotechnology.

C4 Responsive governance and regulatory adaptation

b) Encourage research into the ethical, legal and social dimensions of neurotechnology.

C4 Equipping institutional oversight

c) Promote the further development of ethical guidance and best practices including rigor and reproducibility.

C4 Encouraging responsible business

d) Ensure that oversight and advisory bodies possess appropriate multi-disciplinary expertise for constructive technology assessment, horizon scanning, scenario planning and review of research.

G4 Equipping institutional oversight

e) Develop institutional capacity and mechanisms of technology appraisal and/or foresight to anticipate and evaluate potential neurotechnology outcomes and pathways.

Publications and other resources related to Principle 6

Principle 7: Safeguard personal brain data and other information gained through neurotechnology.

C4 Protecting Data Privacy

To this end, relevant actors should:

a) Provide clear information to the public and research participants about the collection, storage, processing and potential use of personal brain data collected for health purposes.

C4 <u>Protecting Data Privacy</u>

b) Ensure that means of obtaining consent adequate to protect the autonomy of individuals are in place, including consideration of special cases of limited decision-



making capacity.

C4 <u>Protecting Data Privacy</u>

c) Promote opportunities for individuals to choose how their data are used and shared, including options for accessing, amending and deleting personal data.

C4 Protecting Data Privacy

- d) Promote policies that protect personal brain data from being used to discriminate against or to inappropriately exclude certain persons or populations, especially for commercial purposes or in the context of legal processes, employment or insurance.
 - **C4** Anticipating technological change and impacts
 - **C4** Protecting Data Privacy
- e) Protect information gained through the application of neurotechnology from unauthorised use, including through the use of data access agreements when appropriate.
 - **C4** Anticipating technological change and impacts
 - **C4** <u>Protecting Data Privacy</u>
- f) Promote confidentiality and privacy and mitigate security breaches, including through the implementation of rigorous security standards.
 - **C4** <u>Protecting Data Privacy</u>
- g) Ensure not only traceability of data collected and processed but also of medical acts in which neurotechnology is used.
 - **C4** <u>Protecting Data Privacy</u>

Publications and other resources related to Principle 7

Principle 8: Promote cultures of stewardship and trust in neurotechnology across the public and private sector.

To this end, relevant actors should:

- a) Encourage development of best practices and business conduct that promote accountability, transparency, integrity, trustworthiness, responsiveness and safety.
 - **C4** Encouraging responsible business
 - **C4** <u>Developing international standards</u>
- b) Support innovative approaches to social responsibility through the development of accountability mechanisms.
 - **A** Responsive governance and regulatory adaptation
- c) Foster communication in the public sphere that avoids hype, overstatement and unfounded conclusions, both positive and negative, and that discloses interests in a



transparent manner.

C4 <u>Consulting and communicating with citizens</u>

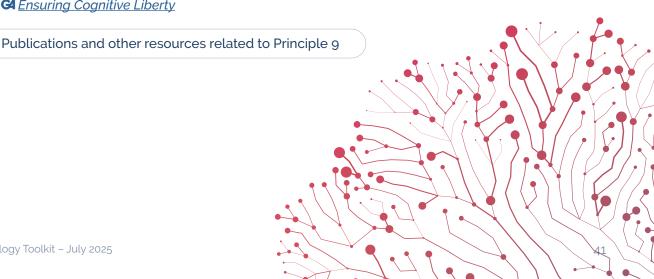
- d) Identify any issues, gaps, and challenges within systems of governance and explore possible solutions through dialogue among regulators, the private sector and the public.
 - **C4** Equipping institutional oversight
- e) Promote trust and trustworthiness through norms, and practices of responsible business conduct.
 - **C4** Encouraging responsible business

Publications and other resources related to Principle 8

Principle 9: Anticipate and monitor the potential unintended use and/or misuse of neurotechnology.

To this end, relevant actors should:

- Promote mechanisms to anticipate, and prevent, potentially harmful, short and longterm unintended uses and impacts before neurotechnologies are deployed.
 - **C4** <u>Anticipating technological change and impacts</u>
- b) Implement safeguards and consider mechanisms to support integrity, autonomy, protection of private life, non-discrimination and dignity of the individual or of groups in the short and/or long term.
 - **C4** Ensuring Cognitive Liberty
- c) Anticipate and prevent activities that seek to influence decision processes of individuals or groups by purposely affecting freedom and self-determination through, for example, intrusive surveillance, unconsented assessment, manipulation of brain states and/or behaviour.
 - **C4** Ensuring Cognitive Liberty
- d) Where possible, take active steps to protect against potential misuse of neurotechnology.
 - **C4** Ensuring Cognitive Liberty





PUBLICATIONS AND OTHER RESOURCES

Principle 1: Promote responsible innovation in neurotechnology to address health challenges.

The **OECD paper** "Responsible innovation in neurotechnology enterprises" (2019), based on insights from the workshop "Minding Neurotechnology: delivering responsible innovation for health and well-being" (2018), examines the benefits and challenges of implementing responsibility frameworks within the private sector and provides an environment for participants to discuss ways to advance responsible neurotechnology innovation. *Read the paper here*.

The **OECD paper** "Brain-computer interfaces and the governance system" (2022) aims to facilitate the development of a responsible and anticipatory governance approach to promoting innovation in BCIs while guiding the trajectory of such technologies through mechanisms including (i) soft law, (ii) standardisation and ethics-by-design approaches, (iii) corporate self-governance and (iv) participatory experiments for upstream governance. *Read the paper here*.

The **chapter** "The OECD approach to responsible innovation" in the edited book *Convergence Mental Health: A Transdisciplinary Approach to Innovation* (2021, p.79-84) discusses the Recommendation and the novelty of its responsible innovation approach. To read the chapter, *find the book here*.

The **collection of essays** "Ethics and Society in Brain Research: Implementing Responsible Research and Innovation (RRI) in the Human Brain Project (HBP)" (2023) was part of the HBP's mission to integrate neuroethics into its research activities. The essays emphasise the importance of using empirical evidence not only to showcase results but also for philosophical reflection. They highlight key findings, personal reflections and lessons learned, and ultimately expands the scope of participation to include more diverse stakeholders. *Read the collection of essays here*.

The **report** "Pioneering Digital Neuroscience: How the 10-year Human Brain Project has transformed brain research" (2023) showcases the trajectory and impact of the Human Brain Project's (HBP's) work following its close in 2023. The report explores how the HBP mobilised existing neuroscience networks to promote data and knowledge sharing and ultimately advance understandings of the brain, brain disease and digital neuroscience. *Read the report here*.

The **strategic plan** "BRAIN 2025: A Scientific Vision" (2014) was developed for the advancement of brain research by the BRAIN Initiative of the US National Institutes of Health (NIH). It outlines the Initiative's philosophy and research priorities as well as the practical elements of their implementation. *Read the plan here*. The **report** "BRAIN 2.0 Neuroethics: Enabling and Enhancing Neuroscience Advances for Society" (2018) was written by a Neuroethics Subgroup based on the review of the strategic plan from 2014 and provides an assessment of ethical issues that may arise from its application. *Read the report here*.



Opinions and reports concerning various topics covered by the French Comité Consultatif National d'Éthique (CCNE) are publicly available on its <u>website here</u>. The CCNE is a national committee whose role is to inform relevant stakeholders of ethical considerations relating to issues of science and health. *Read the CCNE's opinions and reports on neuroscience and neurotechnology here*. Opinion 129, "Contribution of the Comité Consultatif National d'Éthique to the Revision of the Bioethics Law" (2018), synthesises results of the CCNE's consultations with the public which informed the revision of the French Bioethics Law during the same year. *Read Opinion 129 here* (in French) and *a summarised version here* (in English).

The **paper** "Protecting Cognition: Background Paper on Neurotechnology" (2024) by the Australian Human Rights Commission examines the human rights risks posed by neurotechnologies and identifies areas requiring further safeguards and governance to ensure development and deployment that respects human rights. *Read the paper here*.

Resolution 2344 "The brain-computer interface: new rights or new threats to fundamental freedoms?" (2020), adopted by the Council of Europe's Parliamentary Assembly, discusses ethical principles, including safety and precaution, applicable to the development and application of neuro- and BCI- technology. *Read resolution* 2344 here.

The **report** "The Regulation of Neurotechnology" (2022) by the UK Regulatory Horizons Council (RHC) provides fourteen recommendations to the government for anticipatory regulatory reforms that could facilitate the safe and rapid development of neurotechnology. *Read the report here*.

Principle 2: Prioritise assessing safety in the development and use of neurotechnology.

A **two-volume report** by the US Bioethics Commission presents insights from engagements with the scientific community, the public and other stakeholders in the first two years following the launch of the US BRAIN Initiative in 2013. Both volumes strongly endorse the proactive integration of neuroethics into neuroscience research. The first, "Gray Matters: Integrative Approaches for Neuroscience, Ethics and Society" (2014) highlights ethical issues associated with neuroscience research and proposes recommendations for best practices to effectively address concerns and guide future work. *Read volume one here*. The second, "Gray Matters: Topics at the Intersection of Neuroscience, Ethics and Society" (2015) examines the societal implications of advancements in neurotechnology with a particular focus on cognitive enhancement, consent capacity and neuroscience and the legal system. *Read volume two here*.

The **article** "Neuroethics for the National Institutes of Health BRAIN Initiative" (2018) by the Society for Neuroscience outlines the mission of the BRAIN Initiative in the US, focusing on its neuroethics strategy, "BRAIN 2025: A Scientific Vision," and outlining its future steps. *Read the article here*.



Principle 3: Promote the inclusivity of neurotechnology for health.

The **online tool** "Engage2020 Action Catalogue" is a decision support tool that presents different research methods to those wanting to conduct inclusive scientific research. It outlines the strengths and weaknesses of various approaches, their potential to address societal challenges, and ways in which they have been applied before to enable users to decide which would best suit their needs. It is an outcome of the Engage2020 project (2013-15) funded by the European Commission. *Access the tool here*.

The **article** "Stakeholder engagement in European brain research" (2023) by the Lifebrain Consortium presents the results of its investigation into factors influencing brain health, which involved multi-stakeholder activities including an exploration of public perceptions. Participants included patient organisations, research networks, policymakers and members of broader society. It concluded that multi-stakeholder engagement is greatly beneficial to brain research. *Read the article here*.

Principle 4: Foster scientific collaboration in neurotechnology innovation across countries, sectors, and disciplines.

The **roadmap** "The Future of Brain/ Neural Computer Interaction: Horizon 2020" (2015) provides background information on brain-computer interfaces (BCIs) and their potential applications and impact, and highlights considerations for their future development. In so doing, it illustrates the opportunities and challenges they pose as well as areas to think about regarding their regulation. *Read the roadmap here*.

The **white paper** "Standards Roadmap: Neurotechnologies for Brain-Machine Interfacing" (2020) by the IEEE, an international standard-setting body, presents a gap analysis on existing standards in the field, as well as public opinion on neurotechnologies, as gathered from an online survey. It proposes recommendations for standards to prioritise in the context of fast-developing systems and is set up as a living document to allow for its adaptation upon availability of further information. *Read the white paper here*.

Principle 5: Enable societal deliberation on neurotechnology.

The **report** "The landscape of science, ethics and public engagement & their potential for the future" (2021) by the Danish Board of Technology, in collaboration with the Kavli Foundation, explores ways to facilitate communication between experts and more general audiences to enable public engagement with ethical issues in science. *Read the report here*.

The **report** "From our brain to the world: views on the future of neural interfaces" (2019) by the Royal Society presents findings from a public dialogue on the impact of neurotechnology on society. It provides recommendations on communication and



language, ongoing public engagement and outstanding questions to advance public debate on the issue. *Read the report here*.

The **working paper** "Accessible and inclusive public communication: Panorama of practices from OECD countries" (2022) by the OECD Experts Group on Public Communication, in collaboration with the French Government Information Service, presents examples from different countries on facilitating inclusive participation in public communication, particularly for persons with a disability, to ensure their active and uninhibited involvement. *Read the working paper here*.

The **report** "iHuman: Blurring lines between mind and machine" (2019) examines the societal impacts of digital neural interfaces. As part of the UK's Royal Society's iHuman Project, it urges developers and regulators to adopt a responsible approach to emerging products and examines neurotechnology for medical use in contrast with the ethical issues arising from its broader everyday applications. Read the report here. As part of this work, the Royal Society commissioned a public dialogue to gain a greater understanding of public opinion on neural interfaces and their potential impacts. Learn more about the dialogue here.

Online resources by the International Neuroethics Society include books, journals, webinars and multimedia teaching resources to educate those interested in neuroethics and neuroscience. *Access the resources here*.

Principle 6: Enable the capacity of oversight and advisory bodies to address novel issues in neurotechnology.

The **report** "Ethical issues of neurotechnology" (2021) by the International Bioethics Committee of UNESCO explores the interaction between neurotechnology, ethics and human rights, and examines the potential evolution of existing rights in the context of new and emerging technologies. *Read the report here*.

The **report** "Unveiling the neurotechnology landscape: scientific advancements innovations and major trends" (2023) by UNESCO discusses the neurotechnology ecosystem in terms of what is being developed, where and by whom, and analyses how neurotechnology interacts with other technological trajectories, particularly artificial intelligence. *Read the report here*.

The **report** "100 Radical Innovation Breakthroughs for the Future" (2019) provides insights on emerging technologies and practices with strong potential for societal impact and presents policy recommendations for their regulation. It showcases the results of the Horizon Scanning for Radical Innovation Breakthroughs survey by the European Commission, which were combined with insights from foresight projects. Among other topics, it discusses "neuromorphic chips" and "neuroscience of creativity and imagination". *Read the report here*.



Principle 7: Safeguard personal brain data and other information gained through neurotechnology.

The **United Nations report** "Interim report of the Special Rapporteur on freedom of religion and belief, Ahmed Shaheed" (2021) examines the potential for infringement of article 18 (1) of the International Covenant on Civil and Political Rights, namely freedom of thought. It outlines the characteristics of this right before exploring ways in which it might face violation (including through the use of neurotechnology and other forms of emerging tech) before proposing recommendations to various stakeholders on how to protect it. *Read the UN report here*.

The **report** "ICO tech futures: neurotechnology" (2023) by the Information Commissioner's Office (ICO), the UK's data protection regulator, explores possible uses of emerging neurotechnologies and examines the impact of neurodata on individual privacy with a focus on discrimination, informed consent and the importance of regulatory cooperation in enacting ethical standards. *Read the report here*.

The **report** "Big Data and Health" (2017) by UNESCO explores strategies to bolster informed consent when it comes to emerging technologies and provides tailored recommendations to various actors. *Read the report here*.

The **report** "Common Human Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Fields" (2021) by the Council of Europe discusses points raised at the online event "Neurotechnologies and Human Rights Framework: Do We Need New Rights?" hosted by the Council of Europe and the OECD in November 2021, such as the ethical issues surrounding the collection, sharing and processing of brain data. It proposes priority areas for academic attention and policy work. *Read the report here*.

The **Opinion and Action Plan** on "Data Protection and Privacy" (2018) by the EU Human Brain Project (HBP) proposes measures to strengthen data protection in the context of emerging neurotechnologies. It identifies some of the greatest privacy-related concerns which emerged throughout the project, outlines the ethical principles through which to address them and provides a history of data protection in Europe in order to present existing regulations and introduce recommendations for their development. This document was developed in preparation for the launch of the EU GDPR by an interdisciplinary research team in the HBP's Ethics & Society group. *Read the opinion and action plan here*.

The **report** "The Case for Accountability: How it Enables Effective Data Protection and Trust in the Digital Society" (2018) by the Centre for Information Policy Leadership (CIPL) provides insight into the importance and benefits of accountability with regards to personal data with a focus on GDPR, and proposes ways for organisations to implement accountability through the adoption of codes of conduct. *Read the report here*.



The CIPL provides **resources** and tools for companies and regulators to enable stewardship and accountability, such as reports on "Building Accountable AI Programmes: Mapping Emerging Best Practices to the CIPL Accountability Framework" and "Privacy-Enhancing and Privacy-Preserving Technologies: Understanding the Role of PETs and PPTs in the Digital Age." *Find CIPL resources here*.

Principle 8: Promote cultures of stewardship and trust in neurotechnology across the public and private sector.

The Japanese Moonshot R&D Programme developed **two neurotech resources** - a "Neurotech Guidebook" that provides information to the public on developments in neurotechnology, including benefits and challenges, and a "Braintech Evidence Book" targeted at neurotechnology companies and users of their products. Both draw on the OECD Neurotechnology Recommendation and are available in Japanese with an English translation. Read *the Guidebook here* (in English) and *the Evidence Book here* (in English).

The **paper** "Mobilising the private sector for responsible innovation in neurotechnology" (2021) details lessons, emerging practices and open questions for responsible innovation in the private sector. Insights result from three years of policy deliberations in 2018-2020. *Read the paper in Nature Biotechnology here*.

The **OECD paper** "Advancing accountability in AI: Governing and managing risks throughout the lifecycle for trustworthy AI" (2023) explores how risk-management frameworks and values-based principles can be integrated into AI systems at various stages of their lifecycle to promote responsible and trustworthy technologies. *Read the paper here*.

The 2023 edition of **the OECD Guidelines for Multinational Enterprises on Responsible Business Conduct** provide updated recommendations for responsible business conduct across key areas, including technology. *Read the guidelines here*.

Principle 9: Anticipate and monitor the potential unintended use and/or misuse of neurotechnology.

The **report** "Scientific Freedom and Scientific Responsibility: Recommendations for Handling of Security-Relevant Research" (2014), a collaborative work between the German Academy of Sciences (Leopoldina) and the German Research Foundation (DFG), makes a set of recommendations regarding the research and application of dual use technologies. It explores the conflict between research freedom and research ethics, highlighting the potential risks excessive liberty may pose to human dignity, safety and life, and proposes a set of recommendations for ethical conduct that go beyond the basic legal limit. *Read the recommendations here*.

Annex

The **report** "Brain-Computer Interfaces: US Military Applications and Implications, An Initial Assessment" (2020) by the RAND Corporation, a global policy think tank, provides an overview of its research to date. The report draws on insights from the project Security 2040 and includes an assessment of the US Department of Defense's investment into brain-computer interfaces and other such technologies that enable communication between the human brain and external devices for current and future military purposes. *Read the report here*.

The **article** "Opinion on 'Responsible Dual Use: Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology" (2023) by the EU Human Brain Project's (HBP's) Dual Use Working Group suggests applying Responsible Research and Innovation (RRI) practices and dual use research of concern (DURC) frameworks to neurotechnology research in order to reasonably anticipate technologies which may pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, material or national security. *Read the article here*.





CREDITS AND EDITORIAL REMARKS

The OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) developed this Neurotechnology Toolkit throughout 2022-2024. It benefitted from the active participation and contributions from national delegates (in alphabetical order by country): Andrew Atkinson and Natalie Labbé (Canada), Ana Nieto (the EU), Pascal Maigné (France), Karsten Rapsch (Germany), Carmelina Ruggiero (Italy), Kazuhito Oyamada (Japan), MyongHwa Lee (Korea), Luís Melo (Portugal), Anina Henggeler and Will Lawson (UK), and Kate Stevens (US).

David Winickoff and Laura Kreiling led the Secretariat team involved in its development, which also included Lou Lennad and Abby Morales. Nita Farahany, Robinson O. Everett Professor of Law & Philosophy from Duke University, substantially contributed to the conceptualization and drafting of the toolkit. Karen Rommelfanger provided research, writing and review of the text. The graphics design work was done by Yifan Shau.

This document, as well as any data and map included herein, are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

The example, publications and other resources presented in this document are illustrative and non-exhaustive. The Neurotechnology Toolkit is a living document made available under the responsibility of the Director for Science, Technology and Innovation of the OECD and thus will undergo regular manual reviews to ensure information presented remains relevant. The date of the latest review will be indicated on the cover page and in the page footer. Please send your feedback or relevant information to STI.BNCT@oecd.org by 1 September 2024.





Neurotechnology Toolkit

To support policymakers in implementing the OECD Recommendation on Responsible Innovation in Neurotechnology

July 2025

