Recommendation of the Council on Responsible Innovation in Neurotechnology

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Background Information

The Recommendation on Responsible Innovation in Neurotechnology (hereafter the "Recommendation") was adopted by the OECD Council on 11 December 2019 on the proposal of the Committee for Scientific and Technological Policy (CSTP). The first international standard in this domain, the Recommendation aims to guide governments and innovators to anticipate and address the ethical, legal and social challenges raised by novel neurotechnologies while promoting innovation in the field.

The Recommendation embodies nine principles, which focus on:

1. Promoting responsible innovation
2. Prioritising safety assessment
3. Promoting inclusivity
4. Fostering scientific collaboration
5. Enabling societal deliberation
6. Enabling capacity of oversight and advisory bodies
7. Safeguarding personal brain data and other information
8. Promoting cultures of stewardship and trust across the public and private sector
9. Anticipating and monitoring potential unintended use and/or misuse.

The Recommendation seeks to provide guidance at each step of the innovation process – e.g. research, technology transfer, investment, commercialisation, regulation - so that benefits are maximised and risks minimised. It articulates the importance of (1) high-level **values** such as stewardship, trust, safety, and privacy in this technological context, (2) building the capacity of key **institutions** like foresight, oversight and advice bodies, and (3) **processes** of societal deliberation, inclusive innovation, and collaboration.

The Need for an International Standard for Responsible Innovation in Neurotechnology

Novel neurotechnology offers significant potential for the promotion of health, well-being, and economic growth. Mental health is an increasingly important public health concern in OECD Member countries and beyond.Mental and neurological disorders (e.g. Alzheimer's disease and other dementias) cause great human suffering and are increasingly recognised as major causes of death and disability worldwide. They often remain untreated and impose significant economic and social welfare costs, elevating their importance to the highest national and international policy levels.

Neurotechnology is redefining what is possible in terms of monitoring and intervention in clinical and non-clinical settings, with great promise for improving mental health, well-being and productivity. Spearheaded by large national and international flagship initiatives in brain science and fuelled by a clear medical need, research both in the public and private sector has made considerable advances. In particular, the convergence between neuroscience, engineering, digitalisation, and artificial intelligence (AI) is becoming a key driver of innovation and will disrupt existing practices as well as traditional boundaries between medical therapies and consumer markets.

At the same time, neurotechnology raises a range of unique ethical, legal, and societal questions that potential business models will have to address. These questions include issues of (brain) data privacy, the prospects of human enhancement, the regulation and marketing of direct-to-consumer devices, the vulnerability of cognitive patterns for commercial or political manipulation, and further inequalities in use and access. Governance issues surrounding neurotechnology affect the entire innovation pipeline, from fundamental brain research, cognitive neuroscience, and other brain-inspired sciences to questions of commercialisation and marketing.

In order to respond to these issues, the OECD, through its Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT), has been pursuing a five-year project focusing on developing a set of principles for responsible innovation in neurotechnology. These aim to assist governments and innovators in addressing and anticipating the governance challenges raised by mental and neurological disorders and novel neurotechnologies.

The Development of the Recommendation through a 5-year Process

Between 2015 and 2019, the BNCT conducted the project “Neurotechnology and Society” with the objective to:

- Pool ideas, norms, and approaches for achieving more responsible innovation in neurotechnology for health-related applications through dialogue involving researchers, innovators, policy makers, health care professionals, and the public.
- Promote international deliberation, engagement, and transparency on the ethical, legal, societal, regulatory, and economic aspects of neurotechnology development.
- Develop principles for responsible development, integration, and use of new and innovative neurotechnologies for health-related applications.

The Recommendation developed out of a step-wise process of structured consultation and engagement with policymakers, key stakeholders and civil society. A steering group composed of BNCT delegates and appointed experts oversaw a series of workshops featuring experts from different disciplines and sectors, including government, academia, healthcare, civil society, business and philanthropy. The steering group provided guidance throughout the project, including in the textual development of principles for responsible innovation in neurotechnology and their embodiment in the Recommendation.

Implementation and Dissemination of the Recommendation

The implementation of the Recommendation will be supported by the development of practical tools and guidance. A collection of examples of best practices and lessons learned in the field of neurotechnology and other emerging technologies will be developed to assist Adherents in the project of implementation.

In addition, the CSTP, through the BNCT, will serve as a forum for exchanging information on neurotechnology policy and experiences with the implementation of the Recommendation and foster multi-stakeholder and interdisciplinary dialogue on innovation in neurotechnology.

For further information, please consult: https://www.oecd.org/sti/emerging-tech/.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data [OECD/LEGAL/0188]; the Recommendation of the Council concerning Access to Research Data from Public Funding [OECD/LEGAL/0347]; the Recommendation of the Council on the Governance of Clinical Trials [OECD/LEGAL/0397]; the Recommendation of the Council on Digital Security Risk Management for Economic and Social Prosperity [OECD/LEGAL/0415]; the Recommendation of the Council on Integrated Mental Health, Skills and Work Policy [OECD/LEGAL/0420]; the Recommendation of the Council on Health Data Governance [OECD/LEGAL/0433]; the Recommendation of the Council on the OECD Due Diligence Guidance for Responsible Business Conduct [OECD/LEGAL/0443]; the Decision of the Council on the OECD Guidelines for Multinational Enterprises [OECD/LEGAL/0307], and the Recommendation of the Council on Artificial Intelligence [OECD/LEGAL/0449];

HAVING REGARD to the 1948 Universal Declaration of Human Rights;

RECOGNISING that neurotechnology holds great promise for human health and innovation;

RECOGNISING that neurotechnologies developed to prevent, diagnose, and treat mental and neurological disorders in most cases have robust oversight infrastructure to ensure safety and efficacy;

RECOGNISING that the fast-moving and sometimes uncertain pathways of certain neurotechnologies, like other emerging technologies, might require agile forms of governance;

RECOGNISING the importance of public and private investment in brain science and neurotechnology development across disciplines and jurisdictions, and that such investments will support a strong evidence base and innovation in neurotechnology;

RECOGNISING that there are ethical, legal, and societal questions raised by certain applications of neurotechnologies given the perceived centrality of the brain and cognitive function to notions of human identity, freedom of thought, autonomy, privacy, and human flourishing;

RECOGNISING that the possible long-term opportunities and challenges of neurotechnology warrant a broad public discussion about the best future of neurotechnology in society;

CONSIDERING that neurotechnology developed for health purposes can be used in unintended manners;

RECOGNISING that interpretation of personal brain data could potentially influence decisions outside of clinical practice and may perpetuate social inequality;

RECOGNISING that trust in the research enterprise is founded on safety being of paramount importance;

RECOGNISING that given the different cultural understandings of the brain and mind, there may be diverse ways of putting responsible innovation into practice, and that such diversity creates an opportunity for learning;

CONSIDERING that realising responsible innovation in neurotechnology will require concerted action across governmental levels and across the public and private sectors and that the principles set out in this Recommendation may accordingly be relevant to actors in all of these settings;

RECOGNISING that the principles set out in this Recommendation are complementary and should be considered as a whole.

On the proposal of the Committee for Scientific and Technological Policy:

I. **AGREES** that the overall purpose of this Recommendation and the principles it contains is to achieve responsible innovation in neurotechnology for health.

II. **AGREES** that, for the purpose of this Recommendation, the following definitions are used:

- **Actors**: public and private organisations, and individuals who play an active role in neurotechnology innovation, including research, development, uptake, and use.
- **Autonomy**: the freedom to make one's own choices.
- **Cognitive liberty**: the right to mental self-determination.
- **Health**: a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
- **Personal brain data**: data relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health, or mental states.
- **Neurotechnology**: devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons.
- **Safety**: an acceptable level of probable benefits and risks to health.
- **Stakeholders**: all organisations and individuals involved in, or affected by, neurotechnology, directly or indirectly. Actors are a subset of stakeholders.

III. **RECOMMENDS** that Members and non-Members having adhered to this Recommendation (hereafter the "Adherents") promote and implement the following principles for responsible innovation in neurotechnology, which are relevant to all stakeholders and **CALLS ON** all actors to promote and implement, according to their respective roles, the following principles for responsible innovation in neurotechnology:

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.

b) Integrate ethical considerations and take into account public values and concerns at the planning stage and design phase of technological development.

c) Foster alignment of public support and economic incentives for neurotechnology innovation with the greatest health needs.

d) Avoid harm, and show due regard for human rights and societal values, especially privacy, cognitive liberty, and autonomy of individuals.

e) Prevent neurotechnology innovation that seeks to affect freedom and self-determination, particularly where this would foster or exacerbate bias for discrimination or exclusion.

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.

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, safety into research prioritisation processes.

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

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.

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.

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.

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.

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

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.

b) Foster pre-competitive consortia of collaborative research across public research institutions, private non-profit organisations, private sector entities, and patient communities.

c) Support the development of standards and best practices for the technical as well as ethical, legal, and social aspects of innovation in neurotechnology.

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.

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.

b) Engage in multi-stakeholder dialogues and deliberation to ensure diverse inputs into decision-making processes, public policy and governance.

c) Ensure that the results of formal dialogues are considered and taken into account in decision-making wherever possible.

d) Ensure processes for engaging stakeholders are fair, transparent, and predictable.

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

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.

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

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

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

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

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

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.

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

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.

e) Protect information gained through the application of neurotechnology from unauthorised use, including through the use of data access agreements when appropriate.

f) Promote confidentiality and privacy and mitigate security breaches, including through the implementation of rigorous security standards.

g) Ensure not only traceability of data collected and processed but also of medical acts in which neurotechnology is used.

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.

b) Support innovative approaches to social responsibility through the development of accountability mechanisms.

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.

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.

e) Promote trust and trustworthiness through norms, and practices of responsible business conduct.

9. Anticipate and monitor the potential unintended use and/or misuse of neurotechnology. To this end, relevant actors should:

a) Promote mechanisms to anticipate, and prevent, potentially harmful, short and long-term unintended uses and impacts before neurotechnologies are deployed.

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.

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.

d) Where possible, take active steps to protect against potential misuse of neurotechnology.

V. **INVITES** the Secretary-General and Adherents to disseminate this Recommendation.

VI. **INVITES** non-Adherents to take due account of, and adhere to, this Recommendation.

VII. **INVITES** the Committee for Scientific and Technological Policy, through the Working Party on Biotechnology, Nanotechnology and Converging Technologies, to develop further practical guidance on the implementation of this Recommendation.

VIII. **INSTRUCTS** the Committee for Scientific and Technological Policy, through the Working Party on Biotechnology, Nanotechnology and Converging Technologies, to:

a) serve as a forum for exchanging information on neurotechnology policy and experiences with the implementation of this Recommendation and foster multi-stakeholder and interdisciplinary dialogue on innovation in neurotechnology; and

b) monitor the implementation of this Recommendation and report thereon to the Council no later than five years following its adoption and at least every ten years thereafter.

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 460 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions** are adopted by Council and are legally binding on all Members except those which abstain at the time of adoption. They set out specific rights and obligations and may contain monitoring mechanisms.

- **Recommendations** are adopted by Council and are not legally binding. They represent a political commitment to the principles they contain and entail an expectation that Adherents will do their best to implement them.

- **Substantive Outcome Documents** are adopted by the individual listed Adherents rather than by an OECD body, as the outcome of a ministerial, high-level or other meeting within the framework of the Organisation. They usually set general principles or long-term goals and have a solemn character.

- **International Agreements** are negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several other types of substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.