

COUNTRY: Bulgaria - unofficial

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GENERAL COMMENTS

As part of the consultation process the representation of Bulgaria hereby shares comments on the initial draft of UNESCO's Recommendation on the Ethics of Neurotechnology.

In the first place we commend UNESCO for taking up such an initiative and the work of experts who contributed to the content of the document. This Recommendation addresses a rapidly evolving field with tremendous potential. The rapid advancement of neurotechnology, especially when integrated with AI and big data, holds the promise of transformative applications but also bears significant risks. Such potentially transformative developments also present complex ethical challenges that require careful, globally coordinated oversight, as well as mutually agreed governmental policies and legal frameworks.

In this context, a global recommendation from UNESCO could play a pivotal role in encouraging Member States as well as other non-governmental stakeholders to adopt necessary measures. This would help ensure that neurotechnological advancements align with universal human rights principles, established ethical and legal standards in research and medicine, and remain mindful of their impact on human society and the environment.

We hope that our comments and proposed amendments will assist in preparing the second draft for discussion at the upcoming Intergovernmental Meeting at UNESCO.

Here follow some general comments.

AIMS, OBJECTIVES, CONTENT AND SCOPE

The primary and most crucial purpose of the recommendation should be to ensure that the development and application of neurotechnology uphold, protect, and promote human rights, fundamental freedoms, human dignity, but also caters for the environment.

In our understanding, one of the major goals of this recommendation is to promote equitable access, and to propose clear regulatory principles and guidelines that ensure safety for patients and other users. Regarding other areas, particularly the commercial sector and areas of "enhancement", we believe the primary value of the recommendation lies in promoting caution and regulation. In other words, we see a need for the recommendation to address various issues based on the specific policy domain.

We welcome the stance in favour of “allocation of resources for neurotechnology [...] directed toward preventative, diagnostic, therapeutic, assistive, and rehabilitative purposes that benefit the largest number of people and those who stand to gain the most, rather than consumer-driven or commercial applications.” (§22) This position must be consistently reflected throughout the entire text, which maybe ethically ambiguous (i.e. human enhancement). On occasion, the text expresses an almost unreasonable hope for neurotechnology to benefit humanity in general, for instance in phrases about “human flourishing”. This borders on a transhumanist perspective. Since future scenarios within these areas (in particular the commercialized wellness- and health industries) are hard to predict, we believe it is better for the recommendation to take a cautious stance towards such formulations.

FEASIBILITY, IMPLEMENTATION AND RELEVANCE

The level of details should be balanced against the potential for societal, environmental, and technical changes in view of possible implementation hurdles. The different needs, conditions and situations of the Member States must also be carefully considered.

We welcome the approach that all engaged actors in this field are responsible “[...] to ensure the embedding of ethics in all stages of the neurotechnology lifecycle”, which is acknowledged in §19 (b) in **II Aims and Objectives**. However, in the forthcoming chapters, almost exclusively Member States are addressed. To clarify and emphasize that this is a shared responsibility, the recommendation should more explicitly underline the responsibility of each actor involved in this field.

SCOPE, DEFINITIONS AND PERSPECTIVES

The broad definition of neurotechnology (**I.2 Definitions**, §12-§14) has both strengths and weaknesses. A broad definition means that almost all technologies that can predict neural states can fall under this scope. This broad inclusion might benefit from clearer boundaries or examples to distinguish neurotechnology from other general diagnostic or inferential tools.

On the other hand, there might be good reasons for keeping a broad definition for the purpose of future relevance. However, the broader definition, the greater scope. For clarification and avoiding misinterpretation, not at least since this is a very complex field, we believe it would be worthwhile to explain the rationale behind excluding certain medical applications, for instance pharmacological treatment with influence on the nervous system, with the exception for neuropharmacological infusion (§13 b.i).

In addition, we ask for improved clarifications of distinctions between neurotechnology for enhancement and for medical applications (with the purpose of improving the lives for people with medical needs).

The importance of science-based evidence/methods/applications/integrity etc. must be better emphasized. We also ask for consistency in the use of the terms *evidence based*, *scientific evidence* and *robust scientific evidence*, or clarification of their significance in relation to each other. Qualifications of the term consent throughout the text - “free informed”, “only” informed consent”, “fully informed consent”, “affirmative consent”, “voluntary consent”, “free, informed and voluntary consent” should be harmonized.

It is somewhat difficult to understand whether “research” is omitted consciously in some of the paragraphs when only development and deployment of neurotechnology is mentioned. Hence, how the recommendations differentiate between different stages are sometimes unclear (see detailed comments).

Some references to relevant international or global policies/laws are missing, for instance, the World Medical Association’s (WMA) *Declaration of Helsinki* regarding ethical principles for medical research involving human participants, which regulates national laws and regulations in many countries, including Sweden,¹ the *ISO 14155:2020 Clinical Investigation of medical devices for human subjects* and regulations and directives from the European Union such as the *European Union Medical Device Regulation (MDR)* etc.²

AREAS OF POLICY ACTIONS

Although the Member States are ultimately responsible for promoting and ensuring an ethical neurotechnology, the recommendation should clarify that no actors involved in this field can be exempted from responsibility.

As previously mentioned, some of the recommendations and calls for action are very detailed, with risk of missing related issues.

Enhancement, which is an area predicted to grow tremendously and with substantial risks, should be further explored.

SUSTAINABLE DEVELOPMENT

Bulgaria welcomes that the Recommendation addresses sustainability but identifies a need for this area to be further explored, both in a broad sense and with specific emphasis on the environmental dimension. The latter is as important since the recommendation addresses the whole lifecycle of neurotechnology, including mining for materials and AI. Likewise, the social and economic aspects of sustainability and benefit sharing are of great importance and should be given a prominent role. The Recommendation could refer to the Sustainable Goals as expressed in Agenda 2030, and awareness of the interdependent relationship between the three pillars of sustainability (the ecological, the social and the economic).

DISPOSITION AND STRUCTURE

We suggest moving the section **Consideration for specific users**, §103-§121, to its own chapter.

ORIGINAL TEXT	NEW PROPOSED TEXT	COMMENTS
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¹ [WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association](#)

² [ISO 14155:2020 - Clinical investigation of medical devices for human subjects — Good clinical practice; Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex](#)

PREAMBLE	PREAMBLE	PREAMBLE
Paragraph 1	Paragraph 1	Paragraph 1
Recognizing the profound and dynamic impacts of neurotechnology on human kind lives and flourishing, and societies, environment, and ecosystems,	Recognizing the profound and dynamic impacts of neurotechnology on human kind humankind lives and flourishing, and societies, environments, and ecosystems,	
Paragraph 2		
Considering the major and growing global prevalence of neurological and mental health conditions, along with the profound suffering they cause for individuals and societies worldwide,		
Paragraph 3		
Acknowledging the potential of neurotechnology to offer innovative solutions and deliver better preventive and therapeutic treatments for millions, benefitting humanity as a whole and providing opportunities for health improvements in all countries,		
Paragraph 4		
Also considering that neurotechnology raises fundamental ethical issues for instance regarding self-determination, privacy, personal identity, freedom of thought, risk of discrimination, inequality and challenges to democracy, and that justice, trust and fairness must be upheld so that no country and no one should be left behind, either by having fair access to neurotechnology and enjoying their benefits or in the protection against their risks, while recognizing the different circumstances of different countries and respecting the desire of some people not to take part in all technological developments,	Also considering <u>underscoring</u> that neurotechnology must never be used in a way raises fundamental ethical issues that stand in conflict with the universal human rights, for instance regarding self-determination, privacy, personal identity, freedom of thought, and risk of discrimination, inequality and challenges to democracy, and that justice, trust and fairness must be upheld so that no country and no one should be left behind, either by having fair access to neurotechnology and enjoying their benefits or in the protection against their risks, while recognizing the different circumstances of different countries and respecting the desire of some people not to take part in all technological developments,	Our advice is to use a language that much stronger promotes a human based approach. Split this paragraph in three paragraphs. See suggestion below

	Recognizing that neurotechnology raises fundamental ethical issues regarding commercialization of neural data, risks concerning security and data protection, long-term safety, inequality and challenges to democracy	Red text added. Even if the added examples might be exhaustive, we believe it is important to include these crucial points.
	Underlines and that justice, trust and fairness must be upheld so that no country and no one should be left behind, either by having fair access to neurotechnology and enjoying their benefits or in the protection against their risks, while recognizing the different circumstances of different countries and respecting the desire of some people not to take part in all technological developments,	See §9 and §10, that also address geographical matters. Consider collecting all paragraphs on this topic so they come after each other.
Paragraph 5		
Recalling that, by the terms of its Constitution, UNESCO seeks to contribute to peace and security by promoting collaboration among nations through education, the sciences, culture, and communication and information, in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms which are affirmed for the peoples of the world,		
Paragraph 6		
Given the leading role of UNESCO, at the forefront of the international dialogue, knowledge production and standard setting on the ethics of science and technology and bioethics,		

Paragraph 7		
Convinced that the Recommendation presented here, as a standard-setting instrument developed through a global approach, based on international law, focusing on human dignity and human rights, as well as gender equality, social and global justice and development, physical and mental well-being and health, diversity, interconnectedness, global solidarity, fairness, non-discrimination, inclusiveness, and environmental and ecosystem protection, can guide neurotechnology in a responsible direction,		This sentence is very exhaustive and should preferably be split up.
Paragraph 8		
Guided by the purposes and principles of the Charter of the United Nations,		This paragraph should be moved up, maybe begin the Preamble .
Paragraph 9		
Emphasizing that specific attention must be paid to low- and middle-income countries (LMICs), including but not limited to least developed countries (LDCs), landlocked developing countries (LLDCs) and small island developing States (SIDS), as they have their capacity but have been underrepresented in the development and access to neurotechnology,		
Paragraph 10		
Underscoring that global cooperation and solidarity facilitates fair access to neurotechnology and enables the realization of the full potential of neurotechnology, while addressing the ethical challenges, mitigating against potential misuse, and ensuring that national neurotechnology strategies are guided by ethical principles in full respect of international human rights law,	Underscoring that global cooperation and solidarity is crucial to facilitates fair access to neurotechnology and to realize enables the realization of the full potential of neurotechnology, while addressing the ethical challenges, mitigating against potential misuse, and ensuring that national neurotechnology strategies are guided by ethical principles in full respect of international human rights law,	
Paragraph 11		

<p>Noting that ethical guidelines, frameworks and open science promote innovation, development and policies aligned with international human rights law,</p>		
<p>Paragraph 12</p>		
<p>Also recalling that in November 2023, the General Conference of UNESCO, at its 42nd session, adopted 42 C/Resolution 29, by which it mandated the Director-General "to prepare a standard-setting instrument on the ethics of neurotechnology in the form of a recommendation", which is to be submitted to the General Conference at its 43rd session in 2025,</p>		
<p>Paragraph 13</p>		
<p>Bearing in mind the Universal Declaration of Human Rights (1948), the instruments of the international human rights framework, including the Convention Relating to the Status of Refugees (1951), the Discrimination (Employment and Occupation) Convention (1958), the International Convention on the Elimination of All Forms of Racial Discrimination (1965), the International Covenant on Civil and Political Rights (1966), the International Covenant on Economic, Social and Cultural Rights (1966), the Convention on the Elimination of All Forms of Discrimination against Women (1979), the Convention on the Rights of the Child (1989), and the Convention on the Rights of Persons with Disabilities (2006), the Convention against Discrimination in Education (1960), the Convention on the Protection and Promotion of the Diversity of Cultural Expressions (2005), as well as any other relevant international instruments, recommendations and declarations,</p>		
<p>Paragraph 14</p>		
<p>Also noting the United Nations Declaration on the Right to Development (1986); the Declaration on the</p>		

<p>Responsibilities of the Present Generations Towards Future Generations (1997); the Universal Declaration on Bioethics and Human Rights (2005); the United Nations Declaration on the Rights of Indigenous Peoples (2007); the Declaration of Ethical Principles in relation to Climate Change (2017); the Recommendation on Science and Scientific Researchers (2017); the Recommendation on the Ethics of Artificial Intelligence (2021); the Recommendation on Open Science (2021); the Human Rights Council's resolution on "The right to privacy in the digital age" (NHRC/RES/42/15) (2019); the Human Rights Council's resolution on "New and emerging digital technologies and human rights" (NHRC/RES/41/11) (2019), and the UN Guiding Principles on Business and Human Rights (2011),</p>		
<p>Paragraph 15</p>		
<p>Recalling that the 2021 Recommendation on the Ethics of Artificial Intelligence, recognizes ethical questions related to AI-powered systems for neurotechnology and brain-computer interfaces,</p>		
<p>Paragraph 16</p>		
<p>Also conscious of the existing ecosystem of national policies, and other frameworks and initiatives elaborated by relevant United Nations entities, intergovernmental organizations such as OECD, including regional organizations, as well as those by the private sector, professional organizations, non-governmental organizations, and the scientific community, related to the ethics and regulation of neurotechnology,</p>	<p>Also conscious of the existing ecosystem of national policies, and other frameworks and initiatives elaborated by relevant United Nations entities, intergovernmental and regional organizations, as well as those by the private sector, professional organizations, non-governmental organizations, and the scientific community, related to the ethics and regulation of neurotechnology,</p>	<p>Consider removing the OECD. Other organizations might be as equally relevant to acknowledge, and then the recommendation will end up with a long list.</p>
<p>16.1</p>		
<p>Adopts the present Recommendation on the Ethics of neurotechnology on this XXX day of November 2025;</p>		

16.2		
<p>Recommends that Member States, with the support of UNESCO's Secretariat, apply the provisions of this Recommendation by taking appropriate steps, including whatever legislative or other measures may be required, in conformity with the constitutional practice and governing structures of each State, to give effect within their jurisdictions to the principles and norms of the Recommendation in conformity with international law, including international human rights law;</p>		
16.3		
<p>Also recommends that Member States engage all actors, to ensure that they play their respective roles in the implementation of this Recommendation; and bring the Recommendation to the attention of international, regional and national authorities and bodies, research and academic organizations, institutions and organizations in public, private and civil society sectors involved in neurotechnology, so that the development and use of neurotechnology are guided by both sound scientific research as well as ethical analysis and evaluation.</p>		
I. SCOPE OF APPLICATIONS AND DEFINITIONS	I. SCOPE OF APPLICATIONS AND DEFINITIONS	I. SCOPE OF APPLICATIONS AND DEFINITIONS
I.1 SCOPE		<p>We suggest that SCOPE comes after DEFINITIONS and AIMS AND OBJECTIVES</p> <p>This section is also very extensive. Try to condense.</p> <p>See paragraph 3 in SCOPE OF APPLICATION in the Recommendation on the Ethics of AI (2021), which highlights prioritized domains for the recommendation. Something similar</p>

		<p>should be done in this recommendation for clarification.</p> <p>Also see paragraph 4 in SCOPE OF APPLICATION in the Recommendation on the Ethics of AI (2021), which clarifies addressed target groups (“This Recommendation is addressed to Member States, both as AI actors and as authorities responsible for developing legal and regulatory frameworks throughout the entire AI system life cycle, and for promoting business responsibility. It also provides ethical guidance to all AI actors, including the public and private sectors, by providing a basis for an ethical impact assessment of AI systems throughout their life cycle.”)</p>
This Recommendation:	This recommendation applies an ethical, Human Rights based approach to all stages of the life cycles of neurotechnology, and, as such:	
1. Addresses ethical issues related to neurotechnology, as it can have many positive and adverse impacts on human health, human flourishing and on the enjoyment of human rights.	Acknowledges the positive impacts that neurotechnology can have on human health, and, at the same time, addresses the adverse impact of the technology on human health and the enjoyment of human rights....	The positive impacts of neurotechnology on human flourishing and the enjoyment of human rights needs clarification.
2. Considers neurotechnology for people of diverse backgrounds and abilities, and various fields, including health, non-medical direct-to-consumer (DTC), such as wellness devices, neurogaming), addressing various settings where neurotechnology may be utilised.	2. Considers neurotechnology for all people of diverse backgrounds and abilities , and various fields, including health, non-medical direct-to-consumer (DTC), such as wellness devices, (neurogaming), addressing various settings where neurotechnology may be utilised.	
3. Focuses on humans only but acknowledges important considerations that apply to animals in research.		Where in this draft are animals considered besides in this paragraph?
4. Approaches neurotechnology ethics as a systematic normative reflection based on a holistic, multicultural,	4. Approaches neurotechnology ethics as a systematic normative reflection based on a	What is the meaning of normative reflection in this context?

<p>multidisciplinary, pluralistic and evolving framework of interdependent values, principles, and actions that can guide societies in dealing responsibly with the impacts of neurotechnology on human beings, societies, and the environment and ecosystems.</p>	<p>holistic, multicultural, multidisciplinary, pluralistic and evolving framework of interdependent Human Rights based values, principles, and actions that can guide aiming at guiding societies in dealing responsibly with the impacts of neurotechnology on human beings, societies, and the environment and ecosystems.</p>	
<p>a) It considers ethics as a basis for the normative evaluation and guidance of neurotechnology, with human rights, human dignity, well-being, and the prevention of harm as a compass and foundation.</p>		
<p>b) It draws upon a full range of scholarship, commentary and views from neuroscience, medicine, engineering, psychology, ethics, human rights, law, sociology, anthropology and other disciplines.</p>	<p>It draws upon a full range of scholarship, including commentary and views from neuroscience, medicine, engineering, psychology, ethics, human rights, law, sociology, anthropology and other disciplines.</p>	
<p>5. Covers the measurement, recording, and modification of the human nervous system, the handling, analysis, treatment, storage, use and reuse of the data collected, along with other societal and environmental impacts, including the emergence of new cognitive states.</p>		
<p>6. Recognizes that interventions involving the nervous system are very sensitive because the highly complex human nervous system is the coordinating centre of behaviour and mental processes. It enables the exercise of self-determination, the capacity to act as moral agents, to be responsible for actions, cooperate with others, deliberate about collective decisions and develop personality.</p>		
<p>7. Further recognizes that humans develop and flourish in their interaction with other human beings and a nurturing material and cultural environment, highlighting</p>		<p>This paragraph needs clarification. It starts with acknowledging that interaction with other humans and the material and</p>

<p>that autonomy is not just individual but also relational, as it arises from and impacts one's interactions and belonging with the community.</p>		<p>cultural environment is fundamental for our human development, and then addresses autonomy as a state that is both individual and relational. It's very difficult to figure out the message and the essence.</p> <p>The established definition of autonomy, especially in medical law, is the right of adults with capacity to make informed decisions about their own medical care (and concerning non-medical applications of neurotechnology affecting an individual)</p> <p>The autonomy principle is a main guiding principle in medical ethics.</p> <p>A respect for competent decisions by adult patients is also a cornerstone of medical law.</p> <p>The vague definition of autonomy in this paragraph is also poorly aligned to the general understanding of this important concept</p>
<p>8. Addresses the ethical and human rights concerns that arise from the rapid developments and the convergence of neurotechnology with other technologies such as spatial computing, extended reality (XR), artificial intelligence (AI), sensors and semi-conductors. Notably, other biometric data when processed to infer sensory, motor, and mental states raises similar ethical concerns. Therefore, this Recommendation applies to both neurotechnology and the use of cognitive biometric data, ensuring that ethical principles and practices are consistently applied across these domains.</p>		<p>Many of the definitions in this paragraph are unfamiliar to the public and readers without expert knowledge in the field of neurotechnology. Consider adding them to the section of Definitions, that preferably should come before Scope.</p> <p>The paragraph needs to be re-worded.</p>

<p>9. Further addresses the integration of AI with neurotechnology, which can enhance precision and predictive capabilities, such as improving processing speed, reducing cost, optimizing neurotechnology systems. However, it also magnifies ethical threats, including cybersecurity concerns, lack of transparency, the potential for algorithmic bias, and risks to autonomy, mental privacy and of manipulation.</p>		
<p>10. Promotes the peaceful use of neurotechnology and seeks to raise awareness on the profound ethical challenges and threats that come with the military and security applications of neurotechnology. Galls on all concerned to act responsibly with regard to neurotechnology.</p>	<p>[...] Galls on Urges all concerned to act responsibly with regard to neurotechnology.</p>	<p>Regarding the paragraph as a whole: should it be moved to AIMS?</p>
<p>I.2 DEFINITIONS</p>		<p>For pedagogical reasons, the section about DEFINITIONS should preferably come right after the PREAMBLE. There might also be good reasons for adding concepts that need to be explained for the reader.</p>
	<p>For the purpose of this Recommendation:</p>	
<p>11. Nervous system. The nervous system includes the central (brain, spinal cord) and peripheral (somatic, autonomic, enteric) nervous system. Scientific evidence demonstrates that nervous system activity is the basis of sensory, motor, and mental states (which include cognitive, affective, and conative states), and supports consciousness, sleep and the experience of pain. The nervous system activity and structure provide information inherent to all human beings and the community, regardless of gender, ethnicity, language, or religion. The nervous system activity is also instrumental in social and cultural interactions.</p>	<p>11. Nervous system. The nervous system includes the central (brain, cerebellum, brainstem, spinal cord) and peripheral (somatic, autonomic, enteric) nervous system. Scientific evidence demonstrates that nervous system activity is the basis of sensory, motor, and mental states (which include cognitive, affective, and conative states), and supports consciousness, sleep and the experience of pain. The nervous system activity and structure provide information inherent to all human beings and the community, regardless of gender, ethnicity, language, or religion. The nervous system activity is also instrumental in social and cultural interactions.</p>	<p>The terms cerebellum and brainstem should be added in order to be fully correct.</p>

<p>12. Neurotechnology. Neurotechnology refers to devices, systems, and procedures- encompassing both hardware and software-that directly access, monitor, analyze, predict or modulate the nervous system to understand, influence, restore, or anticipate its structure, activity, function, or intentions (speech, motor). Neurotechnology combines elements of neuroscience, engineering, and computing, among others</p>	<p>Neurotechnology refers to devices, systems, and procedures- encompassing both hardware and software- that directly or indirectly measure, access, monitor, analyze, predict or modulate the nervous system to understand, influence, restore, or anticipate its structure, activity, function, or intentions (speech, motor, auditory-, visual- or tactile sensations). Neurotechnology combines elements of neuroscience, engineering, and computing, among others</p>	<p>or indirectly measure should be added to cover so called non-touch and remote methods that may influence the nervous system.</p> <p>The text in the parenthesis (speech, motor) is unclear, suggested additions contributes to clarification.</p> <p>It is unclear what doesn't qualify as neurotechnology in this definition. Since it includes technologies that can predict neural states, almost anything could fall under this scope – even tools like questionnaires. This broad inclusion might benefit from clearer boundaries or examples to distinguish neurotechnology from other general diagnostic or inferential tools. Are police tasers considered as neurotechnology?</p>
<p>13. Neurotechnology spans medical and non-medical applications and includes tools that measure, infer, and influence nervous system activity, whether through direct interaction with the nervous system or by interfacing it with devices and systems. It includes but is not limited to:</p>		
<p>a) Technical tools that measure and analyse physical (i.e., acoustic, electrical, optical, magnetic and/or mechanical), chemical and biological signals associated with the structure of and functional signals from the nervous system. These may be used to identify, record, and/or monitor properties of nervous system activity, understand how the nervous system works, diagnose pathological conditions, or central external devices (brain machine interfaces (BMI), often referred to as brain computer interfaces (BCI)). Of note, both open-loop (i.e., fixed-parameter brain stimulation)</p>	<p>b) Technical tools that measure and analyse physical (i.e., acoustic, electrical, optical, magnetic and/or mechanical), chemical and biological signals associated with the structure of and functional signals from the nervous system (including cell therapy). These may be used to identify, record, and/or monitor properties of nervous system activity, understand how the nervous system works, diagnose pathological conditions, or central</p>	<p>Consider adding cell therapy. And cells that can be conditionally altered by opto or chemogenetics. The cells function can be altered and therefore also change the human feeling and behaviour.</p>

<p>and closed- loop systems (i.e., state dependent stimulation) introduce complex ethical issues.</p>	<p>external devices (brain machine interfaces (BMI), often referred to as brain computer interfaces (BCI). Of note, both open-loop (i.e., fixed-parameter brain stimulation) and closed- loop systems (i.e., state dependent stimulation) introduce complex ethical issues.</p>	
<p>a) (i). Examples include but are not limited to Electroencephalography (EEG), Magnetoencephalography (MEG), Magnetic resonance imaging (MRI), Functional Magnetic resonance imaging (fMRI), Positron emission tomography (PET), Functional Near-infrared spectroscopy (fNIRS), Implanted microelectrodes, Optogenetics, Optical imaging, Diffusion weighted imaging, Calcium imaging, Voltage dye sensors, or Microdialysis.</p>	<p>(i). Examples of measurement methods include but are not limited to Electroencephalography (EEG), Magnetoencephalography (MEG), Magnetic resonance imaging (MRI), Functional Magnetic resonance imaging (fMRI), Diffusion weighted imaging, and other MRI methods, Positron emission tomography (PET), Computed Tomography (CT), Neuronavigation systems, Functional Near-infrared spectroscopy (fNIRS), Implanted microelectrodes, Optogenetics, Optical imaging and monitoring, Calcium imaging, Voltage dye sensors, or Microdialysis.</p>	<p>Please clarify that this section refers to examples: “of measurement methods” fMRI is one type of MRI method/protocol. Several other exists e.g. diffusion weighted imaging. It is also suggested to add: and other MRI methods</p> <p>Computed Tomography (CT) is a common imaging method and has been added.</p> <p>Neuronavigation systems are used together with brain images to calculate anatomical position e.g. during brain surgery and has therefore been added.</p> <p>Since optical monitoring is common, and monitoring was added.</p> <p>Even if the scope is very broad, maybe an explanation of what is excluded, might be to consider.</p>
<p>b) Technical tools that interact with the nervous system to change its activity, for example, to restore sensory input, such as hearing (i.e.,</p>	<p>Technical tools that interact with the nervous system to change its activity, for example, to restore sensory input, such as hearing (i.e.,</p>	<p>DBS and other simulation methods doesn't remove or treat the disorder.</p>

<p>cochlear implants) or Deep Brain Stimulation (DBS) to treat tremors and other pathological conditions. They are meant to either modulate the functions of the nervous system and/or send signals directly to the nervous system by applying acoustic, electrical, magnetic or optical stimulation and/or inhibition of the peripheral or central nervous system.</p>	<p>cochlear implants) or Deep Brain Stimulation (DBS) to treat reduce symptoms of tremor, movement disorders and other pathological symptoms. They are meant to either modulate the functions of the nervous system and/or send signals directly to the nervous system by applying acoustic, electrical, magnetic or optical stimulation and/or inhibition of the peripheral or central nervous system.</p>	<p>More examples of common use have been added.</p> <p>Vagus nerve stimulation can also be added as an example of method.</p> <p>The last parts has been deleted since modulate includes inhibition.</p>
<p>(b). (i). Examples of this neurotechnology are implanted microelectrodes, BMI, DBS, Optogenetic optical stimulation, Transcranial electrical stimulation (tES), Transcranial Magnetic Stimulation (TMS) or Neuropharmacological infusion.</p>	<p>Examples of this neurotechnology are implanted microelectrodes, BMI, DBS, Optogenetic or optical stimulation, Ablation (by ultrasound or other mechanical waves, radiofrequency heating or cryo), Transcranial electrical stimulation (tES), Transcranial Magnetic Stimulation (TMS) or Neuropharmacological infusion.</p>	<p>Optogenetic is one method and optical stimulation without genetic modification is another method, and these should be separated.</p> <p>Ablative methods are not mentioned, they destruct nervous tissue in a controlled way.</p>
<p>14. Of note, several sensor technologies collect data indirectly informing about neural activity. Even if they are not neurotechnology <i>per se</i>, they raise similar ethical and human rights issues as neurotechnology when used to infer mental states. They include but are not limited to eye-tracking, Video Oculography, Typing dynamics, Voice recognition and analysis, Gait analysis, Skin conductance, Heart rate variability, Sleep movement monitoring, Blood pressure measurement, or facial- emotion recognition systems.</p>	<p>Of note, several sensor technologies collect data indirectly informing about neural activity. Even if they are not neurotechnology <i>per se</i>, they already raise similar ethical and human rights issues as neurotechnology when used to infer mental states. They include but are not limited to eye-tracking, Video Oculography, Typing dynamics, Voice recognition and analysis, Gait analysis, Skin conductance, Heart rate variability, Sleep movement monitoring, Blood pressure measurement, or facial- emotion recognition systems.</p>	<p>It is perhaps important to emphasize that detailed monitoring of human behaviour (eye-tracking, tracking of gestures and facial expressions, voice/speech characteristics, language use etc.) is currently a much more effective method to reveal hidden internal states, intentions, responses to external stimuli relating to inner goals, preferences etc. than any existing neurotechnological technique.</p> <p>Thus, a regulation of such applications could become a blueprint for future neurotechnological applications (relates to §16 below)</p>
<p>15. Neural data. Neural data are qualitative and quantitative data about the structure, activity and function of the nervous system. They encompass data</p>		<p>The implications of direct correlates in this context needs to be either clarified, or left out.</p>

relating to a nervous system's activity, including both direct measurements of neuronal structure, activity and/or function (i.e., neuronal firing or averaged bioelectric signals from EEG) and indirect functional indicators (i.e., blood flow in fMRI and fNIRS). At the neurobiological level, neural data are the most direct correlates of mental states.		
16. Cognitive Biometric Data. Neural data, along with data collected by non-neural biometric technologies can be processed to infer mental states, which this Recommendation refers to as "cognitive biometric data".		It could be mentioned here or at other suitable place in the document that non-neural parameters can be GPS positions, eye-tracking data, gait parameters, posture etc.
17. Whole lifecycle. Neurotechnology should be considered from the early stages of mining for materials, prototyping, research, design and development to deployment and use, including maintenance, operation; trade, financing, monitoring and evaluation, validation, end-of-use, disassembly, termination, disposal and recycling. The whole lifecycle of neurotechnology includes its convergence with other technologies and the diversity of actors who are involved in every stage.		
II. AIMS AND OBJECTIVES		
18. This Recommendation has been created with the aim of guiding the development and use of neurotechnology in ways that are ethical, safe and effective for the good of humanity, individuals, communities, societies, the environment and ecosystems, and to prevent harm in the present and the future based on international law, in particular the Charter of the United Nations and international human rights law.		Consider leaving out. Feels redundant.
19. The objectives of this Recommendation are:		
(a) to ensure the protection, promotion and respect of human rights and fundamental freedoms, human dignity and equality, including gender equality, and to respect cultural diversity during the whole neurotechnology lifecycle;		

<p>(b) to guide the actions of Member States, individuals, groups, communities, institutions, private sector companies and every other relevant actor to ensure the embedding of ethics in all stages of the neurotechnology lifecycle;</p>		<p>All actors addressed here, besides Member States, i.e. individuals, groups, communities, institutions, private sector companies and every other relevant actor, should consequently be addressed in the recommendation, when appropriate.</p>
<p>(c) to ensure that neurotechnology in its whole lifecycle is evidence-based, reliable and reproducible;</p>	<p>to ensure that neurotechnology in its whole lifecycle is evidence-based science based, reliable and reproducible;</p>	<p>The term evidence-based has a specific meaning in medical usage, i.e. does not mean “based on evidence” but rather based on evidence collected and interpreted in a specific manner that includes striving for randomized clinical trials as the gold standard.</p> <p>Science-based is more accurate in this context.</p> <p>Also see §100 and §136.</p>
<p>(d) to provide a universal framework that not only articulates values and principles, but also translates into concrete policy recommendations and effective implementation to guide Member States in their engagement with neurotechnology in its whole lifecycle, consistent with their obligations under international human rights law and other international standards;</p>		
<p>(e) to foster multi-stakeholder, multidisciplinary and pluralistic dialogue and consensus building about ethical issues relating to neurotechnology;</p>	<p>to foster a multi-stakeholder, multidisciplinary and pluralistic dialogue and consensus building about ethical issues relating to neurotechnology;</p>	
<p>(f) to promote justice and equitable access to developments and knowledge in the field of neurotechnology and the sharing of benefits;</p>		<p>What is the message here? Is this referring to neurotechnology for all kind of purposes, including enhancement? This paragraph needs to be adjusted in order to not give that impression.</p>

<p>(g) to ensure accountability and solidarity among all actors to prevent misuse of neurotechnology and to uphold human rights and ethical standards.</p>		
<p>III. VALUES AND PRINCIPLES</p>		<p>Suggestion: Consider begin this chapter with common statements that are applicable to all areas/dimensions in order to avoid repetitions and duplications.</p> <p>Some of the paragraphs also overlaps with IV AREAS OF POLICY ACTION or could fit there as well.</p>
<p>III.1 VALUES</p>		<p>The difference between VALUES and ETHICAL PRINCIPLES AND HUMAN RIGHTS is unclear and must be refined.</p>
<p>III.1.1 Respect, protection and promotion of human rights, fundamental freedoms and human dignity</p>		<p>Human rights return in III.2. Ethical Principles and Human Rights.</p>
<p>20. The inviolable and inherent dignity of every human being is the foundation of universal human rights and fundamental freedoms. Respect, protection, and promotion of human dignity, as established by international human rights law, are essential in the whole lifecycle of neurotechnology. Dignity encompasses the recognition of the intrinsic and equal worth of each person. Neurotechnology must never be used in ways that objectify, exploit individual vulnerabilities, or undermine the dignity or rights of any individual, including people living in vulnerable situations.</p>		
<p>III.1.2 Promoting human health and well-being</p>		
<p>21. Prioritizing the development and application of neurotechnology that promotes comprehensive human health and well-being, viewing health as a holistic state of physical, mental, and social well-being.</p>	<p>Prioritizing research, development, and application of neurotechnology that promotes comprehensive human health and well-being, viewing health as</p>	<p>Maybe move highlighted text to DEFINITIONS?</p>

	a holistic state of physical, mental, and social well-being.	
22. The responsible allocation of resources for neurotechnology should be directed toward preventative, diagnostic, therapeutic, assistive, and rehabilitative purposes that benefit the largest number of people and those who stand to gain the most, rather than consumer-driven or commercial applications.	The responsible allocation of resources for neurotechnology should be directed towards preventative, diagnostic, therapeutic, assistive, and rehabilitative purposes that benefit the largest number of people and those who stand to gain the most, rather than consumer-driven or commercial applications.	This is very important. Neurotechnology for the benefit of those who gain most from the technology must be in the centre of this recommendation. Compare §25 where neurotechnology in a general sense is promoted as something that unconditionally benefits humanity.
III.1.3 Ensuring and respecting diversity and fairness		
23. Respect for diversity and fairness, must be upheld in the whole lifecycle of neurotechnology. Special consideration should be given to neurodiversity, minority groups, Indigenous Peoples, and underrepresented voices.	23. Respect for diversity and fairness, must be upheld in the whole lifecycle of neurotechnology. Special consideration should be given to neurodiversity, minority groups, Indigenous Peoples, and underrepresented voices-groups of peoples.	
24. Given that widely recognized neurotechnological innovation largely occurs in the urban well- resourced sector, specific attention to underserved and marginalised people is crucial to prevent bias, ongoing disparities in healthcare, stigma, neglect, and disrespect. Technological assimilation, or using technology as a tool of colonisation (a term the Recommendation refers to as "technological colonialism"), can threaten cultural diversity and heritage, therefore must be protected against.	Given that widely recognized neurotechnological innovation largely occurs in the urban well- resourced sector, specific attention to underserved and marginalised people is crucial to prevent bias, ongoing disparities in healthcare, stigma, neglect, and disrespect. Technological assimilation, or using technology as a tool of colonisation (a term the Recommendation refers to as "technological colonialism"), can threaten cultural diversity and heritage, therefore must be protected against.	Add a definition of "technological colonisation" to DEFINITIONS .
25. Equitable access to neurotechnology should be prioritized globally, ensuring that its benefits are accessible to all, regardless of socioeconomic status or geographical location. Special attention must be given to low- and middle-income countries, resource-constrained settings, and marginalised communities, including the specific needs of different groups, ages, segments, cultural systems, languages, communities,		The requirement of equitable access to neurotechnology needs to be specified. Equitable access to medical treatment is certainly to be desired, but not all potential uses of neurotechnology may be desirable.

and marginalised and vulnerable populations, people with disabilities, neurological disorders, and mental health conditions.		
26. Individuals and groups should be allowed to make lifestyle choices, express beliefs and opinions, share personal experiences, and participate in co-designing technologies, provided that these choices are made in ways that respect the rights of others.	26. Individuals and groups of peoples should be allowed to make lifestyle choices, express beliefs and opinions, share personal experiences, and participate in co-designing technologies, provided that these choices are made in ways that respect the rights of others.	What is the purpose of this paragraph? As it is worded now, it gives the impression that UNESCO promotes non-scientifically based experiments as long as those involved respect the rights of others.
III.1.4 Consideration for cross-cultural perspectives on human knowledge and its sharing		This section (§27-§28) can be removed. The essence can be communicated in other paragraphs/sections.
27. Respectful knowledge sharing on the human nervous system and its functions across communities and cultures fosters trust and strengthens global cohesion in the pursuit of health and quality of life.		Important to clarify that respectful knowledge sharing must follow the principles of open science in accordance with UNESCO's recommendation on Open Science (2021).
28. It is essential that any research and development involving diverse groups and communities is done with their permission and guidance, and conducted with their full prior and informed consent and partnership in ways that serve their interests and respect their traditional knowledge and epistemic contributions.		How does this translate to practice? Permission of a whole group/community seems broad.
III.1.5 Commitment to peace, fairness and justice in society		
29. The use of neurotechnology should be used to promote, not undermine freedom of thought especially in situations where refusal to use the technology could lead to competitive disadvantage. Such interferences include but are not limited to the use of force, threats, undisclosed access, manipulation, or any scenario where consent is compromised, including as a result of power imbalances.		The text refers to the need for "consent" where established medical ethics would require something more, namely "informed consent". See §28 where informed consent it used.
30. The use of neurotechnology should be particularly scrutinized to avoid uses that segregate, objectify or		

subordinate individuals or communities, reduce social cohesion by exacerbating pre- existing inequalities or generating novel inequalities that divide and antagonize individuals against each other, and thereby threaten the coexistence between humans, other living beings and the natural environment.		
III.1.6 Global Solidarity and International Cooperation		
31. The Recommendation should guide all actors in the development, deployment and use of neurotechnology to act in solidarity and call for accountability in instances where neurotechnology may be misused in ways that threaten human rights.		Is research exempted here? It would be good to clarify.
32. International cooperation is essential to addressing cross-border issues related to neurotechnology. Particular attention must be given to differing perspectives on acceptable use to prevent abuse and uphold global ethical standards.	International cooperation is essential to addressing cross-border issues related to neurotechnology. Particular attention must be given to differing perspectives on acceptable use to prevent abuse and uphold global ethical standards.	Yellow marked sentence needs clarification. How and why must particular attention be given to differing perspectives on acceptable use in order to prevent abuse and uphold global ethical standards? What kind of different perspectives are referred to?
III.1.7 Sustainability		
33. Considering that sustainability requires that neurotechnology be developed and used with a deep respect for environmental stewardship, prioritizing the minimisation of ecological harm throughout the lifecycle of the materials used, including, for mining extraction, data processing and storage, recycling and disposal practices.	33. Neurotechnology must Considering that sustainability requires that neurotechnology be developed and used with a deep respect for environmental stewardship, ensuring/safeguarding that prioritizing the minimisation of ecological harm is minimized/avoided throughout the lifecycle of the materials used, including, for That includes mining extraction, data processing and storage, recycling and disposal practices.	
34. The unregulated development of neurotechnology, especially for non-medical purposes, might lead to disproportionate consumption of resources and energy and waste production.		This paragraph must be reworded into an aspiration or position.
35. Respect for Indigenous rights, in accordance with the United Nations Declaration on the Rights of	35. Respect for Indigenous rights, in accordance with the United Nations	

<p>Indigenous Peoples (UNDRIP), requires that neurotechnology, through its whole lifecycle, be guided by a profound respect for Indigenous rights, ensuring that their lands (including during mining), knowledge, communal rights, and privacy are honoured in all activities, including those related to resource extraction.</p>	<p>Declaration on the Rights of Indigenous Peoples (UNDRIP), requires that neurotechnology, through its whole lifecycle, be is guided by a profound respect for Indigenous rights, ensuring that their lands (including during mining), knowledge, communal rights, and privacy are honoured in all activities, including those related to resource extraction.</p>	
<p>III.1.8 Integrity and Responsibility</p>		
<p>36. Integrity requires that all actors in the whole lifecycle of neurotechnology field act with ethical steadfastness. It includes adhering to ethical guidelines and ensuring that all actions align with both professional standards and societal values.</p>		<p>Is this VALUE or POLICY?</p>
<p>37. Integrity includes a commitment to taking responsibility for one's actions and being accountable for their outcomes. This involves not only acknowledging successes but also owning up to mistakes and taking corrective actions when necessary.</p>		
<p>38. Scientific integrity is the commitment to the rigorous pursuit of truth through evidence-based, objective and transparent research practices. It ensures that all scientific endeavours are conducted with honesty, accuracy, and respect for the scientific method of disciplines relevant for neurotechnology.</p>		<p>Consider moving to DEFINITIONS</p>
<p>III.2 ETHICAL PRINCIPLES AND HUMAN RIGHTS</p>		
<p>39. This Recommendation embraces a human-centred approach through fundamental ethical principles including but not limited to self-determination, agency, freedom of thought, privacy, cognitive liberty, personal and collective identity, trustworthiness, respect, reciprocity, and justice. Furthermore, it incorporates the respect, promotion and protection of human rights.</p>		
<p>III.2.1 Beneficence, Proportionality and Do No Harm</p>		

<p>40. Neurotechnology should promote health and well-being, and empower individuals to make informed decisions about their nervous system and mental health while fostering a better understanding of themselves.</p>		<p>§40- §42 The text about enhancement (medical interventions that provide functionality beyond normal human functionality) is unclear. The phrase in 40§ that neurotechnology should "empower individuals to make informed decisions about their nervous system and mental health" gives the impression of allowing for enhancements. The text in 42§ mentions that enhancement may involve medical risks but does not exclude such risk-taking, whereas 41§ says that neurotechnology should not cause harms. From the viewpoint of established medical ethics, the principle of non-maleficence excludes the performance of enhancing interventions with significant medical risks. It is surprising that this standpoint is not clearly supported in the document.</p>
<p>41. Neurotechnology should contribute to human flourishing without causing harm or subordination, whether physically, economically, socially, politically, culturally, or mentally. The "do no harm" principle must guide the whole lifecycle of neurotechnology, ensuring that the quality of life is protected and promoted.</p>		<p>See comments above.</p>
<p>42. Embracing neurotechnology for enhancement may lead to the risk of not only unexpected damage to the nervous system, but also to amplified inequalities within society.</p>		<p>This paragraph must be reworded and much clearer distance itself from enhancement and its risks. The paragraph also, at least partly, overlaps with the IV.16 Enhancement.</p>
<p>43. Any restrictions to human rights must meet all applicable requirements under human rights law, including the principles of legality, legitimate aim, necessity and proportionality.</p>		<p>This paragraph is redundant and should be left out.</p>
<p>44. The principles of proportionality, balance and legitimacy should govern the use of neurotechnology</p>		<p>Is this VALUE or POLICY?</p>

<p>and the data it enables, to ensure their use is: (a) appropriate and proportional to the objective and expected benefits that are aimed to be achieved; (b) do not infringe upon the foundational values of this document; (c) appropriate to the context and target user group; (d) based on safety principles and rigorous scientific evidence.</p>		
<p>III.2.2 Self-determination and the Freedom of Thought</p>		
<p>45. Throughout the whole lifecycle of neurotechnology, the protection and promotion of the rights of freedom of thought, and self-determination must be secured.</p>		
<p>46. Individuals have the right to make free, informed, and voluntary decisions about their engagement with neurotechnology throughout the whole lifecycle, in accordance with international human rights law and other international standards, including the right to refuse or withdraw from its use, at any time, ensuring their autonomy and respect for their decision-making capacity is upheld and where surrogate consent is used, the best interests of the affected individual are considered. Individuals who are enrolled in research should be informed of potential side effects and given the opportunity to disclose if they have any contraindications for the procedures used. Informed consent procedures should be affirmative, dynamic, and require opt-in, comprehensive and transparent providing detailed information about the purposes, risks, benefits, alternatives, and possible outcomes of the technology in all its application domains, ensuring that consent is voluntary and that individuals fully understand the implications for their privacy, autonomy, and well-being.</p>		<p>This description appears to be closer to the medical ethical concept of autonomy.</p> <p>'Self-determination' is for most people in medicine and psychology probably more related to explaining the driving forces behind motivation (SDT theory)</p> <p>See comment §7 above.</p> <p>The part about the right of individuals who take part in a clinical trial does not mention their right to retain a medically useful treatment that they received in a trial, if they so wish. In several trials with implanted neurotechnological devices, participants who could not themselves pay for continued treatment were forced to have a well-functioning device surgically removed at the end of the trial.³ The rights of trial patients to continued treatment should be supported in the document.</p>

³ Sven Ove Hansson, "The ethics of explantation", BMC Medical Ethics, 22:121, 2021. Link: <https://rdcu.be/cxqdl>

<p>47. Neurotechnology should never be used to exert undue influence or manipulation, whether through force, coercion, or other means that compromise self-determination and freedom of thought. This protection covers both the internal processing of thoughts and their external expression, ensuring freedom from any interference.</p>		
<p>III.2.3 Protection of Neural and Cognitive Biometric Data for Mental Privacy</p>		
<p>48. Neurotechnology and cognitive biometric technologies raise issues pertaining to the right to privacy due to their increasing ability to collect direct and indirect data about the nervous system that is uniquely sensitive because they can be processed and analysed to provide deep insights in the processes that underpin our mental states and behaviour, including self-awareness and introspection. As it becomes increasingly difficult to anonymize data, there remains persistent risks of misuse of this data by revealing neurobiological correlates of diseases, disorders, or general mental states without the authorization of the person from whom data are collected.</p>		<p>Very long sentence and difficult to grasp.</p> <p>This is correct, but mainly for cognitive biometric technologies (see comment §14 above).</p>
<p>49. Mental privacy is fundamental for the protection of human dignity, personal identity, and agency. The collection, processing, modification, and sharing of neural data must be conducted with free and informed consent, in ways that respect the ethical and human rights principles outlined in this Recommendation.</p>	<p>49. Mental privacy is fundamental for the protection of human dignity, personal identity, and agency. In order to protect mental privacy, the collection, processing, modification, and sharing of neural data must be conducted with free and informed consent, in ways that safeguards and respect the ethical and human rights principles outlined in this Recommendation.</p>	<p>Crossed out sentence is important, but could be moved to an introductory part of VALUES AND PRINCIPLES, if such a section is added. Mental privacy is fundamental for the protection of human dignity, personal identity, and agency.</p> <p>Provide more concrete examples of potential violations of mental privacy, such as unauthorized access to neural data, discriminatory use of brain-based information, and manipulation of mental states</p>
<p>50. There should be clear safeguards against the misuse or unauthorised access of neural and cognitive biometric data, including affirmative consent, data minimization and purpose specification, data rights</p>		

(such as rights to access, correct and delete), and data security, particularly in contexts where such data might be aggregated with other sources.		
III.2.4 Non-Discrimination and Inclusivity		
51. All actors involved in the whole lifecycle of neurotechnology, particularly in its interface with other technologies like AI, must commit to upholding ethical principles that prevent discrimination, stigmatisation, targeting, or exploitation of any individuals or groups, particularly those in vulnerable situations.		
52. There is a shared responsibility to ensure that these technologies do not perpetuate or amplify existing inequalities or create new forms of discrimination based on neurological or mental characteristics, or other grounds protected under human rights law.		
53. Non-inclusive technological development and standardisation may drive a trend toward homogenisation and the dominance of neurotypicality and capacities that may threaten cultural and collective identity.		Shouldn't this statement be followed by a recommendation?
54. Garnering the trust and acceptance of communities in the whole lifecycle of neurotechnology requires transparent engagement with the public, seeking their input and validation to align these technologies with societal values and the common good.		This sentence is vague.
55. Discrimination on any grounds, including intellectual differences or those related to atypicality, should be condemned. Neurotechnology should not be used to inform, justify, or reify such discrimination. Care should be taken to evaluate neurotechnology solutions promoted through governments for essential services such as education.	55. Discrimination on any grounds, including intellectual differences or those related to atypicality, should be condemned. Neurotechnology should must not be used to inform, justify, or reify such discrimination. Care should be taken to evaluate neurotechnology solutions promoted through governments for essential services such as education.	Yellow marked sentence is difficult to understand. Is it neurotechnological solutions or evaluations of neurotechnological solutions that should be carefully conducted? If the latter, explain why. §67 and §136-138: Here the use of neurotechnology in education is discussed without any mention of the specific neurotechnologies that could be used for education. In §138 it is proposed

		that “neurotechnology in educational settings” could include technologies that need “an assessment of reversibility on the nervous system” and could give rise to “dependency or de-skilling”. Nothing is said about which these technologies are.
56. Neurotechnology should not be used to perpetuate stereotypes, stigma, or discrimination against older persons.	56. Neurotechnology should not be used to perpetuate stereotypes, stigma, or discrimination against elder any persons or groups of people.	This should apply to everyone.
III.2.5 Accountability		
57. Maintaining trust and integrity throughout the whole lifecycle of neurotechnology requires all actors to adhere to the highest ethical standards, remain open to feedback, be committed to adjusting practices in response to new evidence or ethical concerns, and be held accountable for their actions.	57. Maintaining trust and integrity throughout the whole lifecycle of neurotechnology requires all actors to adhere to the highest ethical standards, remain open to feedback, be committed to adjusting practices in response to new scientific evidence or ethical concerns, and be held accountable for their actions.	Very important to underline that design, adjustments etc. must be scientifically based. “Evidence” is too vague in this context, since it is quite often used carelessly to give the appearance of a scientific approach.
58. Accountability is grounded in responsibility, clear and transparent communication, and a duty to anticipate and address potential harms-whether short-term, long-term or arising from unintended use and impact.		Remove or re-word? This is a general description of accountability.
59. A commitment to accountability requires global, governmental, societal and collective action to ensure those harmed by neurotechnology have access to justice, and that those responsible for wrongdoing are required to take meaningful steps to identify, prevent, mitigate and account for how they address and redress their adverse human rights impacts, including through corrective actions and reparations.		How should accountability be addressed within different stages of development? I.e. research, development, deployment? A differentiation is missing.
III.2.6 Trustworthiness and Transparency		
60. To guarantee the respect, promotion and protection of human rights and fundamental freedoms, all actors throughout the whole lifecycle of neurotechnology must		The message here is also applicable on other areas, such as for instance Accountability, Non-Discrimination

<p>ensure that their activities are transparent, grounded in scientific evidence, and aligned with international principles of responsible conduct and scientific integrity. This includes preventing the replication or amplification of biases, ensuring that neurotechnology is traceable and explainable, its capacities and limitations are accurately portrayed, the conditions for accountability are clearly defined, adhering to ethical guidelines in research and development, including the registration of trials, fair participant selection, and approval by independent ethics committees.</p>		<p>and Inclusivity, Integrity and Responsibility.</p> <p>Who defines the conditions for accountability?</p>
<p>III.2.7 Epistemic Justice, Inclusive Engagement and Public Empowerment</p>		
<p>61. Ensuring fair and equitable distribution and creation of knowledge about neurotechnology, including recognizing diverse ways of knowing, and that all individuals and communities can participate in its creation, sharing, and applications.</p>	<p>61. Ensuring fair and equitable distribution and creation of knowledge about neurotechnology, including recognizing diverse ways of knowing, and that all individuals and communities can participate in its creation, sharing, and applications.</p>	<p>Delete diverse ways of knowing since knowledge should be science-based.</p>
<p>62. Promoting open and accessible education, along with public and community engagement, to ensure diverse populations can gain and exchange knowledge about nervous system functioning, mental health, and medical and non-medical applications and tools of neurotechnology.</p>		<p>Here it is very important to underline that knowledge must be scientifically based and with public good interest in mind.</p>
<p>63. Effective public and community engagement throughout the whole lifecycle of neurotechnology requires respect for diversity, including linguistic, social, cultural, heritage, and identity, to respect different ways of knowing and understanding. This respect for diversity ensures that the knowledge and perspectives of diverse communities are valued and included in decision-making processes, and respects self-determination.</p>	<p>63. Effective public and community engagement throughout the whole lifecycle of neurotechnology requires respect for diversity, including linguistic, social, cultural, heritage, and identity, to respect different ways of knowing and understanding. This respect for diversity ensures that the knowledge and perspectives of diverse communities are valued and included in decision-making processes, and respects self-determination.</p>	<p>Again, “respect different ways of knowing and understanding” is promoted. What’s the purpose and implications in this context? Does it also include non-science based ways of knowing and understanding?</p> <p>Respect for diversity is generally important but cannot be promoted when it comes to knowledge in neurotechnology, that must be science based.</p>

<p>64. Grounding education in human rights ensures that the knowledge shared and produced respects the rights of all individuals, preventing epistemic injustice where certain groups may be marginalized or excluded from knowledge production and dissemination.</p>		<p>This claim is quite far-fetched; education in human rights do not necessarily ensures that knowledge sharing and production respects the rights of all individuals etc.</p>
<p>65. All communities should have a voice in decisions that affect them, particularly when it comes to the development and use of neurotechnology.</p>		<p>This is vague. Does this refer to all kinds of neurotechnology and all kinds of communities, including those that wants to develop and use neurotechnology for enhancement and/or for commercial purpose?</p>
<p>III.2.8 Best Interest of the Child and Protection of future generations</p>		<p>Consider merging this part to IV.6, where CHILDREN AND ADOLESCNETS also is addressed.</p>
<p>66. The nervous system is rapidly evolving during childhood and critically changing during adolescence, which makes it crucial to preserve the privacy, self-determination and the right of children and adolescents to participate in decisions that affect them. Technology should be rigorously assessed to ensure it serves the best interests, well-being and healthy development of children, as they grow into autonomous individuals and safeguard the rights of future generations by ensuring that today's decisions promote their future wellbeing.</p>		
<p>67. From an ethical perspective, while recognizing the potential benefits of neurotechnology for early diagnosis, instruction, education, and continuous learning, it is equally important to make a commitment to the holistic development of the child. This includes nurturing their social lite, fostering meaningful relationships, and promoting a healthy lifestyle encompassing nutrition and physical activity.</p>	<p>From an ethical perspective, while recognizing the potential benefits of neurotechnology for early diagnosis, instruction, education, and continuous learning, it is equally important to make a commitment to the holistic development of the child. This includes nurturing their social lite, fostering meaningful relationships, and promoting a healthy lifestyle encompassing nutrition, sleep, and physical activity and access to nature.</p>	<p>The text felt incomplete. Brain research suggests that a healthy lifestyle should also prioritize sleep and access to nature.</p>
<p>III.2.9 Global and social justice, enjoying the benefits of scientific progress and its application</p>		

<p>68. Access to and benefits arising from research and development in neurotechnology must be shared equitably among all contributors to that research and development, with a particular focus on ensuring global distribution that promotes fairness and reduces disparities.</p>	<p>68. Access to and benefits arising from science based research and development in neurotechnology must be shared equitably among all contributors to ensure that research and development, with a particular focus on ensuring global distribution that promotes fairness and reduces disparities.</p>	<p>Important to underline that research and development must be science based. This paragraph could also go under IV AREAS OF POLICY ACTION.</p>
<p>69. Neurotechnology developments should be leveraged to reduce global health inequities. These technologies should serve as catalysts for improving the quality of life, particularly in resource-limited settings.</p>		<p>This paragraph is based on the assumption that neurotechnology can contribute to reducing global health inequalities. For this to be credible, it would have to be shown that access to neurotechnology is a priority for healthcare in low- and middle income countries. The claim that neurotechnologies can “serve as catalysts” would need an explanation of how this could happen.</p>
<p>70. Research, development, and trials in neurotechnology must adhere to the highest ethical standards, ensuring the non-exploitative participation of all individuals involved. This includes safeguarding the rights and well-being of participants, and patients and their caregivers, as well as ensuring the ethical collection and use of data. Special attention should be given to ensure that those contributing to research and development have their fair share of the benefits and do not bear disproportionately the risks.</p>		<p>Are there any risks of using disproportionately in this context, i.e. is this a word open for interpretations that can counteract the objectives of this recommendation in general and of this paragraph in particular?</p> <p>participants, and patients and their caregivers - Are they also considered as contributors ?</p>
<p>71. Efforts, including international cooperation, should be made to overcome, and never take advantage of, the lack of necessary technological or medical infrastructure, education and skills, as well as ethical-legal frameworks, particularly in LMICs, LDCs, LLDCs and SIDS, affecting communities.</p>		
<p>72. The development and impact assessment of novel neurotechnology should consider the implementation of human-centred paradigms in which end-users are not</p>		<p>What are the implications of this paragraph? The paragraph is vague.</p>

merely passive recipients of the technologies but active co-shapers on an equal footing.		End-users should be clarified, maybe in DEFINITIONS .
IV. AREAS OF POLICY ACTIONS		<p>In order to avoid repetition and to condense the text, this chapter could preferably begin with paragraphs that address issues that are applicable to and relevant for all areas, ex. cross country collaboration, multi stakeholder perspective etc.</p> <p>Throughout this chapter, it is the Member States that are held responsible. In some cases, this is correct. In other cases, other actors should be addressed (for instance employers in section IV.14 Labour and Employment).</p> <p>Finally, try to avoid repeating values and ethical principles etc. that already have been addressed. This chapter should instead focus on how these values and principles should be applied into policies and actions.</p>
IV.1 GOVERNMENT INVESTMENT, USE AND REGULATION		
73. Member States, private actors and international institutions should actively support the research, development, and deployment of neurotechnology for the public good. Investments should prioritize applications that foster human flourishing, and the use of which respects, promotes and protects individual and collective human rights. This commitment should include funding for interdisciplinary research that not only advances neurotechnological innovation but also studies the ethical, legal, social, environmental and cultural implications of these technologies, and supports the implementation and clinical translation of	Member States, private actors and international institutions should actively support the science based research, development, and deployment of neurotechnology for the public good. Investments should prioritize applications that foster human health and well-being flourishing , and the use of which respects, promotes and protects individual and collective human rights. This commitment should include funding for interdisciplinary research that not only advances	<p>Until today, medical applications are by far the most important use of these technologies. The deployment of neurotechnology for the public good therefore needs to have a strong medical focus, including access to these new treatment approaches for everyone in society – based on the individual’s medical needs.</p> <p>The requirement that member states should support the development of</p>

<p>technological prototypes. Particular attention should be given to the development and implementation of adequate technical, institutional, procedural and other safeguards to ensure that they equitably benefit society and that human rights are upheld.</p>	<p>neurotechnological innovation but also studies the ethical, legal, social, environmental and cultural implications of these technologies, and supports the implementation and clinical translation of technological prototypes. Particular attention should be given to the development and implementation of adequate technical, institutional, procedural and other safeguards to ensure that they equitably benefit society and that human rights are upheld.</p>	<p>neurotechnology that fosters “human flourishing” is too vague to be meaningful.</p>
<p>74. Member States should establish clear prohibitions against the use of neurotechnology in contexts that violate individual and collective human rights. Member States should conduct human rights due diligence, including regular, comprehensive human rights impact assessments, concerning neurotechnology that they develop, design, deploy, use, sell, operate or procure, in order to prevent and mitigate their adverse human rights impacts. Specifically, neurotechnology should not be used for purposes such as non-consensual interrogation in law enforcement, criminal and civil justice, development or deployment of weapons targeted at the nervous system, social control, attempts at coercive behavioural conformity based on personal beliefs or thoughts, political or other opinion, gender identity or sexual orientation, or surveillance of mental states, among others. Governments should adopt legislation that ensures neurotechnology is deployed responsibly, and based on human rights, with robust oversight mechanisms to enforce adherence to these restrictions and protect mental privacy and freedom of thought for all individuals. These policies should be developed in consultation with diverse actors, including civil society, end-users, neurotechnology experts, ethicists, and human rights advocates, to ensure broad consensus and respect for global human rights norms.</p>	<p>Member States should establish clear prohibitions against the use of neurotechnology in contexts that violate individual and collective human rights. Member States should conduct human rights due diligence, including regular, comprehensive human rights impact assessments, concerning neurotechnology that they develop, design, deploy, use, sell, operate or procure, in order to prevent and mitigate their adverse human rights impacts.</p> <p>---</p> <p>Specifically, neurotechnology should not be used for purposes such as non-consensual interrogation in law enforcement, criminal and civil justice, development or deployment of weapons targeted at the nervous system, social control, attempts at coercive behavioural conformity based on personal beliefs or thoughts, political or other opinion, gender identity or sexual orientation, or surveillance of mental states, among others.</p> <p>---</p> <p>Governments should adopt legislation that ensures neurotechnology is deployed responsibly, and based on human rights,</p>	<p>The paragraph is very long. Maybe split into three paragraphs as suggested.</p> <p>They in this context is a bit confusing. Does They refer to the Member States (i.e. governments/the state) or to actors operating within a state? Preferably, actors operating within a state should be included.</p> <p>That part of the sentence should be clarified. What does that mean “contexts that violate individual and collective human rights” ?</p>

	<p>with robust oversight mechanisms to enforce adherence to these restrictions and protect mental privacy and freedom of thought for all individuals. These policies should be developed in consultation with diverse actors, including civil society, end-users, neurotechnology experts, ethicists, and human rights advocates, to ensure broad consensus and respect for global human rights norms.</p>	
<p>75. Member States should ensure transparency and accountability in their support, oversight, and regulation of neurotechnology, particularly in publicly funded initiatives such as brain research and development programs. While recognizing the limitations in disclosing certain sensitive information, governments should require government sponsored neurotechnology projects to publicly disclose the objectives, methodologies, intended uses, and societal impacts of their neurotechnology initiatives wherever possible. This transparency is crucial for fostering public trust and ensuring that neurotechnology advances are aligned with ethical standards and human rights.</p>		<p>This paragraph is problematic. Distinctions regarding transparency and accountability should not be made based on funding (public or private). Such a distinction might stand in conflict with the Recommendation on Open Science and general scientific standard procedures and give advantages to private funded research.</p> <p>The phrase “[...] recognizing the limitations in disclosing certain sensitive information [...]” is problematic from an Open Science perspective, since it gives companies mandate to prevent researchers from publishing material/data that may be sensitive to the company. Sensitive information and limitations needs to be clarified.</p>
<p>76. Member States should apply a comprehensive approach to regulatory and policy measures to protect against human rights harms related to neurotechnology developed, marketed, operated or used by the private sector. This includes legislative and regulatory measures and accompanying guidance, incentives, and transparency requirements. This comprehensive approach should also require human rights due diligence, ensuring that businesses identify, prevent,</p>		<p>Consider modifying this paragraph so it applies to all actors – private as well as public. A lot of research and medical care is taken place in public institutions (hospitals and universities). Otherwise, clearly underline that this specific paragraph is addressed to the private sector.</p>

<p>mitigate, and account for their adverse human rights impacts through context-dependent processes, including human rights impact assessments, meaningful public and community engagement, and transparent communications.</p>		
<p>77. Member States should ensure that any use of neurotechnology in the justice system, including its consideration by the judiciary should be grounded in robust scientific evidence, be implemented ethically in accordance with human rights, and be aimed at promoting public safety while protecting the rights and dignity of all those involved. This requires respect for fundamental rights, such as human dignity, bodily integrity, confidentiality of personal data, due process and fair trial rights, including the presumption of innocence, and the right against self-incrimination, as well as freedom from torture and ill-treatment, the right to privacy, and the right to freedom of thought.</p>	<p>77. Member States should ensure that any use of neurotechnology in the justice system, including its consideration by the judiciary, should be grounded in scientific evidence, be implemented ethically in accordance with human rights, and be aimed at promoting public safety while protecting the rights and dignity of all those involved. This requires respect for fundamental rights, such as human dignity, bodily integrity, confidentiality of personal data, due process, and fair trial rights, including the presumption of innocence, and the right against self-incrimination, as well as freedom from torture and ill-treatment, the right to privacy, and the right to freedom of thought.</p>	<p>This is the first time that robust scientific evidence is used. Shouldn't this apply to all areas, and especially to the medical field? Are there any deliberate reasons for making a distinction "robust scientific evidence" and "scientific evidence"?</p> <p>The paragraph is also very long, it would benefit from being shortened.</p> <p>In addition, informed consent should be included.</p>
<p>78. Member States should establish comprehensive incentive structures, such as tax incentives, grants, and awards, with a particular focus on encouraging the construction and development of manufacturing, computational resources, and data analytics capabilities within public research institutions and small and medium enterprises (SMEs). Member States should also incentivize and support partnerships that leverage the computational resources and data analytics capabilities of private firms to advance public research goals. These incentives should prioritize rewarding transparency, participatory development processes, and contributions to societal benefits, aiming to foster an environment where public institutions and companies innovate responsibly and align with human flourishing goals.</p>		<p>This paragraph demands that all Member States should have "incentive structures, such as tax incentives, grants, and awards" that support "computational resources" and certain other capabilities. This may not be an appropriate demand on all member states, since their industrial and fiscal policies may have to take other issues into account, such as resource limitations.</p>

<p>79. Member States should establish a coordinated, cross-sectoral approach to assessing the impacts of neurotechnology across the whole lifecycle. This approach should include, but is not limited to:</p>		<p>The sustainability/the environmental aspects of neurotechnology should be highlighted in a separate paragraph.</p>
<p>a) Economic Impact Assessments: Conducted by relevant national bodies responsible for economic and labor policies to assess how neurotechnology impacts economic growth, jobs, social justice, and environmental sustainability;</p>		
<p>b) Benefit-Risk Assessments: Managed by entities responsible for public health, medical research, and consumer protections, these assessments should rigorously evaluate the risks and benefits associated with the development, deployment, and use of neurotechnology, including research, clinical applications, and consumer products. The process should include thorough documentation, ethical oversight, and continuous monitoring to ensure the safety, well-being, and equitable treatment of all individuals involved;</p>		
<p>c) Privacy Impact Assessments (PIAs): under the oversight of relevant national authorities or agencies responsible for data protection and privacy, these assessments should evaluate and mitigate risks to individuals' mental privacy posed by neurotechnology. This includes ensuring that appropriate safeguards are in place to protect neural and cognitive biometric data in compliance with national and international privacy standards, and the data policy practices discussed herein;</p>		
<p>d) Human Rights Impact Assessments (HRIAs): with oversight from relevant national human</p>		

<p>rights institutions or international bodies, identify, prevent, and address potential human rights impacts of neurotechnology. The process should ensure that neurotechnology respects and promotes human rights, with particular attention to vulnerable people and people living in vulnerable situations. HRIAs should involve meaningful public and community engagement to incorporate diverse perspectives.</p>		
<p>80. Member States should promote equitable access to neurotechnology worldwide. To achieve such goals, efforts should be made to support the reduction of final costs for end users, pursue the development, adoption and continuous support of non-proprietary software solutions, and explore reimbursement strategies or subsidisation commensurate with conventions in local jurisdictions, in sectors of crucial potential benefits.</p>		<p>This paragraph requires that member states should “support the reduction of final costs for end users” of neurotechnology. This requirement has no restriction to specific types of neurotechnology. It is reasonable to demand such government support for medical uses, but not beyond that and especially not for enhancement or entertainment. It’s a huge difference between neurotechnology for medical purpose that can save lives or facilitate the lives of severely ill individuals, compared to treatments on healthy persons based on their desire to boost their health.</p> <p>In addition, the definition of end-users should be explained earlier in the text, maybe in Definitions.</p>
<p>81. Member States should adopt agile regulatory frameworks, including the use of regulatory sandboxes-controlled environments for developing, testing, and evaluating neurotechnology-in response to rapid advancements in neurotechnology and its convergence with other technologies such as AI, spatial computing, and immersive technologies. These sandboxes should be used to explore innovative applications, particularly</p>		<p>It is questionable whether Member States could and should be held responsible for using sandbox environments to develop all types of neurotechnology. Member States can/should be urged to introduce laws and other incentives that ensure ethical, safe, and sustainable neurotechnology, but this does not</p>

<p>in workplace settings, with appropriate ethical oversight provided by regulatory bodies or national authorities. These frameworks should facilitate innovation, ensure ethical data processing, and safeguard rights by incorporating mechanisms for regular monitoring, evaluation, and dynamic policy adjustments in line with technological and ethical developments.</p>		<p>necessarily mean that it is the Member States themselves who should be responsible for implementing the sandboxes. In the case of the private sector, including the entertainment and wellness industries, that responsibility should lie with the companies.</p>
<p>IV.2 DATA POLICY</p>		
<p>82. Member States should develop a robust regulatory and legal framework to govern the collection, processing, sharing, and all other uses of neural and cognitive biometric data. This and existing frameworks should recognize this data to be both personal and sensitive data in medical and non-medical contexts.</p>		<p>It is important to emphasize that the sharing of data in a scientific context is extremely important for medical science. Thus, regulations need to balance the potential gains for humanity against the right to personal integrity. This relates to §85 and §87 below</p>
<p>83. Member States should ensure that their existing privacy policies comprehensively cover stringent safeguards for individuals' neural and cognitive biometric data. If current policies do not adequately address these areas, Member States should adopt targeted legislation or regulatory frameworks to secure these protections. These safeguards should for example include affirmative informed consent, data minimization and purpose limitation, data rights (including the right to access, correct, and delete data), and stringent data security measures, such as advanced cybersecurity protocols to prevent unauthorized access and breaches. Such legislation or frameworks should prohibit the practice of tying access to goods or services to the disclosure of neural and cognitive biometric data, require explicit opt-in for any data sharing, and forbid the use of such data for targeted advertising without the individual's explicit, affirmative informed consent.</p>		<p>The concern is clear but the paragraph is very long, detailed and difficult to grasp.</p>
<p>84. Member States should develop and implement specific policies to reduce the ecological footprint of neurotechnology, particularly in relation to large-scale</p>	<p>84. Member States should develop and implement specific policies to reduce which ensure that the ecological footprints of</p>	<p>Environmental sustainability must be better pronounced.</p>

<p>data centers and computing resources used for processing and storage of neural and cognitive biometric data. These policies should emphasise data minimisation, ensuring that only the necessary amount of data is collected and processed, and promote the proportional use of neurotechnology, aligning its deployment with genuine needs and minimising unnecessary environmental impact. Measures should include optimising energy efficiency, using renewable energy sources, promoting the recycling and sustainable disposal of neurotechnology-related equipment, and ensuring the rehabilitation of affected environments.</p>	<p>neurotechnology are sustainable, particularly in relation to large-scale data centers and computing resources used for processing and storage of neural and cognitive biometric data. These policies should emphasise data minimisation, ensuring that only the necessary amount of data is collected and processed, and promote the proportional use of neurotechnology, aligning its deployment with genuine needs and minimising unnecessary environmental impact. Measures These policies should include optimising energy efficiency, using renewable energy sources, promoting the recycling and sustainable disposal of neurotechnology-related equipment, and ensuring the rehabilitation of affected environments.</p>	
<p>85. Member States should support and incentivise the development and implementation of technological innovations and design standards for neurotechnology that prioritize the protection of mental privacy, such as state-of-the-art encryption, secure databases with multi-factor authentication, cutting-edge anonymization techniques, and edge-processing and storage (processing and storing data closer to where it is being generated), leading to greater action-led results in real time storage of neural and cognitive biometric data.</p>		<p>What is the definition of cutting-edge anonymization techniques in this context? Needs to be clarified.</p>
<p>86. Member States should incentivise neurotechnology manufacturers to prioritize privacy and ethics by design, requiring the incorporation of privacy-preserving technologies as default features in their devices.</p>		
<p>87. Member States should encourage ethical data sharing by establishing secure, data repositories for neural and cognitive biometric data used in research. These repositories should meet stringent cybersecurity, data privacy, and ethical use standards (including data minimisation and purpose limitations), tiered access</p>		<p>Between which parties should the data be shared? Who should have access to the data? Needs to be clarified.</p>

and other privacy-enhancing approaches. Appropriate funding mechanisms should be established for the curation and maintenance of data and data governance processes streamlined.		
88. Member States should prioritize efforts to reduce obstacles to cross-border data sharing in neurotechnology research, working towards greater alignment of data protection standards, particularly concerning neural and cognitive biometric data, by establishing clear protocols for data transfer that ensure secure and compliant data exchanges across borders, and standards for interoperability of data, including governance frameworks for data sharing.		
89. Member States should consider specific guidelines for the ethical use of neural and cognitive biometric data in AI development and research, including consent procedures for uses of neural and cognitive biometric data in training and application of AI models, ensuring transparency and respecting individual and community rights.		should consider is rather weak.
IV.3 INTELLECTUAL PROPERTY (IP)		This section is too detailed.
90. Member States should adopt policies to ensure that neural and cognitive biometric data, as individual human activity derivatives, are not subject to proprietary rights. IP protection should only apply to original data compilations (created through a process of aggregation, organization, or selection, resulting in a new dataset) that meet strict and ethical criteria.		Can neural and cognitive biometric data should remain property of the individuals who's, data has been collected.
91. Member States should collaboratively establish clear, harmonised guidelines for IP rights applicable to neurotechnology on an international scale. These guidelines should address the patentability of AI-generated inventions and the ethical implications of IP laws, ensuring they promote global accessibility and innovation.		

<p>92. Member States should ensure that all actors adopt IP management strategies that encourage innovation and avoid overly restrictive patent use, fostering an open innovation ecosystem. This approach should continuously adapt to the evolving landscape of neurotechnology. The impact of IP policies on the neurotechnology sector should be continuously monitored to ensure they stimulate innovation while ensuring ethical use and broad accessibility.</p>		<p>Difficult to understand the essence and implication of marked text. Does it stand in conflict with norms/laws regarding patent protection and copyright?</p>
<p>93. Member States should foster an environment of co-creation in neurotechnology, by facilitating policies and incentives for co-ownership and preferential licensing agreements to ensure equitable compensation and recognition for all contributors.</p>		<p>It is not clear who benefits from this recommendation. To what extent does this fall within the scope?</p>
<p>94. Member States should adopt policies with respect to open science that balance the protection of IP with the promotion of immediate publication of results and data sharing. Particularly with the convergence of digital technologies and the increasing concentration of those innovations in industry sectors, this balance is crucial to ensure that IP protection mechanisms do not hinder scientific research, innovation, and the wide dissemination of knowledge and new technologies. As a basic rule of equitable partnership, when Indigenous Peoples are involved in neurotechnology research and development, open science processes, IP management strategy, should be developed in collaboration with them from the beginning.</p>		
<p>IV.4 CYBERSECURITY</p>		
<p>95. Member States should collaborate internationally to establish comprehensive standards for cybersecurity across all neurotechnology domains. These standards should encompass hardware, software, and data security measures to protect against potential cyber threats. By implementing uniform cybersecurity standards, Member States should ensure the integrity, confidentiality, security, and availability of neural data,</p>		

<p>as well as enhance user trust and confidence in neurotechnology devices. Additionally, these standards should evolve in tandem with technological advancements and emerging cyber threats to maintain robust protection against evolving risks.</p>		
<p>96. Member States should employ red-teaming exercises-adversarial challenges to test the efficacy of security systems-as a proactive measure to assess and enhance the safety, security, and resilience of neurotechnology systems. By conducting regular red-teaming exercises, Member States should proactively identify and address security gaps, test incident response procedures, and strengthen the overall safety and cybersecurity posture of neurotechnology devices.</p>		
<p>IV.5 COMMUNICATION, PARTICIPATION, AND INFORMATION</p>		<p>This section can be condensed. Seems like many paragraphs address the same/similar topics, for instance §97 and §99, and §98 and §101.</p> <p>In addition, factors regarding open and accessible education, public and community engagement are already addressed in III.2.7 Epistemic Justice, Inclusive Engagement and Public Empowerment (§61-§65).</p> <p>In the UNESCO Recommendation on the Ethics of AI (2021), public participation, awareness and understanding of AI technologies etc., is addressed under Awareness and literacy (§44-45), while Communication and Information is addressed as Policy Area 9 (§112-115). Consider making a similar distinction.</p>
<p>97. Member States should promote communication and develop engagement policies for neurotechnology that foster informed, inclusive, and respectful dialogue between researchers, developers, diverse users, and</p>		

<p>the broader public to respect individual and community rights, promote public trust, and harness the collective intelligence and diversity of communities.</p>		
<p>98. Member States should collaborate with international organizations, educational institutions, and private and non-governmental entities to develop and disseminate accessible and engaging educational materials tailored to diverse audiences to bridge knowledge gaps, particularly in underserved regions about the nervous system and mental health functioning, as well as the benefits and risks of neurotechnology. These programs should aim to increase public understanding of the technologies' functionality, safety, efficacy, and societal impact, empowering individuals to make informed decisions and to enable their ethical reflection about their use of neurotechnology.</p>		
<p>99. Member States should implement public and community engagement processes that facilitate genuine mutual learning and collaboration throughout the whole lifecycle of neurotechnology. These processes should include regular and inclusive consultations with a wide array of actors. The aim of these engagements should be to inform policy development, shape ethical guidelines, increase public awareness and understanding, align investment priorities, and ensure that neurotechnology deployment aligns with public interests and values. Special attention should be given to involving groups traditionally underrepresented in technological policymaking, thereby fostering responsible innovation in the field.</p>		
<p>100. Member states should collaborate in the co-creation of accurate, precise, and accessible language and terminology for discussing neurotechnology that involves actors from diverse backgrounds to ensure that the language used is inclusive, non-stigmatizing, and accurately reflects the technologies' capabilities and limitations. Member States should establish regulatory frameworks that require clear and ethical communication standards for neurotechnology. These</p>		<p>The term “evidence-based” has a specific meaning in medical usage, i.e. does not mean “based on evidence” but rather based on evidence collected and interpreted in a specific manner that includes striving for randomized clinical trials as the gold standard.</p>

<p>frameworks should require evidence-based reporting of capabilities, risks, and limitations across all applications to avoid exaggeration of claims, including but not limited to applications in sleep, attention, memory, and emotional regulation. Within these frameworks should be specific guidelines for ethical marketing and protocols for responsible communications about early-stage research and emerging technologies.</p>		<p>Science-based is more accurate in this context.</p> <p>Also see §19c and §136</p>
<p>101. Member States should develop policies that foster effective collaboration between end- users, researchers and innovators throughout the whole lifecycle of neurotechnology product development, with special focus given to the places where the neurotechnology is being developed. These policies should mandate the creation of diverse advisory panels, including representatives from various user groups and respecting neurodiversity. Member States should also establish platforms for ongoing dialogue and feedback between users, researchers and developers. Advisory panels should be involved in the process of developing and testing new neurotechnology products to optimize device efficacy, usability, longevity, and sustainability. This collaborative approach aims to ensure that innovations in neurotechnology are context-compatible and meet the needs of diverse user populations.</p>		<p>This paragraph can be condensed. It seems like the same message is repeated, but with different wordings.</p>
<p>102. Member States should develop age-appropriate, contextually-appropriate, culturally- appropriate, and linguistically-appropriate education about neurotechnology. This should include training modules to aid in the supportive use of these technologies at home, both for the user and for caregivers and family members.</p>	<p>Member States should develop age-appropriate, contextually-appropriate, culturally- appropriate, and linguistically-appropriate science based education about neurotechnology that is age-, contextually, culturally and linguistically appropriate. This should include training modules to aid in the supportive use of these technologies at home, both for the user and for caregivers and family members.</p>	<p>Medical technologies or technologies in general? Can Member State be held responsible for educating and supporting healthy individuals to use neurotechnological tools for boosting their health, ability etc?</p> <p>Add that education must be scientifically based and arranged by established actors, preferably acknowledged science- or medical institutions/centres or universities.</p>

CONSIDERATION FOR SPECIFIC USERS		<p>We suggest that this section begins with recommendations that are applicable to all, and then address issues that are unique for selected users.</p> <p>Also consider moving this section to a separate chapter.</p>
IV.6 CHILDREN AND ADOLESCENTS		
<p>103. Member States should promote healthy brain development through policies that evaluate the impact of neurotechnology on children and adolescents.</p>	<p>Member States should promote ensure healthy brain development through policies that evaluate the impact of neurotechnology on children and adolescents.</p>	<p>should promote is too vague. Also see comment on §106.</p>
<p>104. Member States should safeguard children and adolescents from implicit and explicit coercion to use neurotechnology. Member States should pay attention to the autonomy of children and adolescents through informed consent and assent that is adapted to and respectful of age and decision-making capacity.</p>	<p>Member States should must safeguard children and adolescents from implicit and explicit coercion to use neurotechnology. Member States should pay attention to the autonomy of children and adolescents through informed consent and assent that is adapted to and respectful of age and decision-making capacity.</p>	<p>should pay attention is too vague.</p>
<p>105. Member States should fund research and development grants focused on creating user- friendly assistive neurotechnology tailored for children and adolescents with disabilities. These projects should involve children, adolescents, parents and caregivers in the design process to ensure the technologies meet their specific needs. Educational programs should be developed to teach children and adolescents and their caregivers how to effectively use and maintain these technologies, with support available in multiple languages and accessible without discriminating against those who either cannot or choose not to engage with the proposed technology.</p>		<p>We welcome strong support to children and adolescents with disabilities (incl. their families and caregivers) regarding user-friendly assistive neurotechnology.</p> <p>However, we are not sure that this recommendation should pinpoint methods and efforts such as educational programs. If remained, educational programs should be defined.</p>
<p>106. Member States should ensure research involves strict oversight and close follow-up of all neurotechnology research involving children and</p>		<p>This paragraph about research on children omits the most basic requirement that established medical research ethics</p>

<p>adolescents. This oversight is crucial during the developmental phases of childhood to address and mitigate any unforeseen long- term effects. Such research must include comprehensive monitoring protocols and periodic evaluations to ensure the ongoing safety and well-being of young participants, taking into account their unique developmental needs and vulnerabilities. In the framework of research, involving children and adolescents in medically vulnerable situations (i.e., children in epilepsy monitoring units), special attention will be given to consent and assent, particularly considering particular aspects of research (time, iterations) to prevent any form of instrumentalization.</p>		<p>has on research on children (and all individuals who are unable to give their informed consent), namely that research that can be performed on adult subjects should not be performed on children. On the other hand, there is a need for more clinical research on children. Important that the recommendation shows awareness of this dilemma/tension</p>
<p>107. Member States should enact specific regulations that prohibit the use of marketing techniques-such as neuromarketing, biometric emotional analytics, immersive advertising, and virtual or augmented reality advertising-that rely on sensitive neural and cognitive biometric data collected from children and adolescents. Recognizing the heightened vulnerability of children and adolescents in digital environments, these regulations must explicitly forbid any practices that use such data to influence or exploit children and adolescents.</p>	<p>Member States should enact specific regulations that prohibit the use of marketing techniques-such as neuromarketing, biometric emotional analytics, immersive advertising, and virtual or augmented reality advertising-that rely on sensitive neural and cognitive biometric data collected from children and adolescents.</p> <p>-----</p> <p>Recognizing the heightened vulnerability of children and adolescents in digital environments, and with regards to children's and adolescents' developing brains, especially in areas related to decision-making, these regulations must explicitly forbid any practices that use such data to influence or exploit children and adolescents.</p> <p>---</p> <p>To effectively implement and support this prohibition, it is strongly recommended to foster collaboration among neuroscientists, psychologists, ethicists, and policymakers to</p>	<p>We suggest expanding this paragraph with this extra text to incorporate additional neuroscientific and ethical considerations. This expansion would provide a more comprehensive understanding of the risks associated with these marketing techniques and strengthen the rationale for their prohibition when targeting children and adolescents.</p> <p>Maybe split into two paragraphs as suggested.</p>

	ensure the prohibition is comprehensive and effectively enforced across all relevant digital platforms and technologies.	
IV.7 OLDER PERSONS		
108. Member States should promote healthy aging and support elderly individuals by funding and implementing evidence-based programs that integrate neurotechnology into routine care. These programs should involve the entire support ecosystem, including family, caregivers, and medical teams, to enhance quality of life. Priority should be given to developing and implementing tools that prevent, delay, and treat age-related health conditions, impairments, and neurodegenerative diseases. Member States should ensure that access to these neurotechnology programs is equitable and does not exacerbate socioeconomic inequalities.	Member States should promote healthy aging and support elderly individuals by funding and implementing science based evidence-based programs that integrate neurotechnology into routine care. These programs should involve the entire support ecosystem, including family, caregivers, and medical teams, to enhance quality of life. Priority should be given to developing and implementing tools that prevent, delay, and treat age-related health conditions, impairments, and neurodegenerative diseases. Member States should ensure that access to these neurotechnology programs is equitable and does not exacerbate socioeconomic inequalities. Member States should strive to provide uniform access to these neurotechnology programs across all regions within their territories, including rural and remote areas, to ensure equal availability and prevent geographical disparities in care quality and outcomes.	Important point. But may be hard to implement in states without a publicly funded/weak health system The term equitable in this context requires further clarification. It is unclear whether it solely addresses socioeconomic equity or encompasses a broader scope of equality, including geographical, cultural, and other relevant factors. A more precise definition would enhance the understanding and implementation of this recommendation. It should be clarified that Member States' responsibility to "promote healthy aging and support elderly individuals by funding and implementing evidence-based programs that integrate neurotechnology into routine care" must be restricted to/focused on programs that are the best means to achieve the goals of geriatric and nursing care. It cannot be Member States' responsibility to promote healthy aging, delay or prevent age-related health conditions to "stay fit and young".
109. Member States should establish guidelines for neurotechnology design sensitive to the needs of older adults, carefully considering human-computer interface factors for usability (such as fonts, buttons, and colour) and experience for enhanced visual and auditory cues.		The section seems incomplete. Consider adding hardware design and functionality in order to include the physical/material aspects.

<p>110. Member States should preserve, support, and promote autonomous decision-making for older people using neurotechnology for sensorimotor and cognitive support. The consent process should accommodate potential cognitive challenges faced by older adults, ensuring that consent is informed, ongoing, and adaptable to changing health conditions. Policies should be in place to ensure that assistive neurotechnology recognize changing cognitive capacities over time and respect users' preferences.</p>		<p>The information given, has to be adapted to the culture, language and education of the patient</p>
<p>111. Member States should develop ethical guidelines to ensure that neurotechnology such as robotic caregivers enhance rather than replace human interaction, particularly in the care of individuals with neurodegeneration. These guidelines should emphasize the augmentation of human care, not its replacement.</p>		
IV.8 WOMEN AND GENDER		
<p>112. Member States should adopt and enforce comprehensive policies that promote and respect gender equality and diversity in the whole lifecycle of neurotechnology. The policies should prioritize inclusive research for addressing women and gender specific needs and differences, require targeted data collection and analysis, include education and training programmes an inclusive research practices, ensure public and community engagement with women and gender health experts and advocacy groups and, incentivise gender responsive technology design, to meet the needs and conditions specific to women and gender minorities. Affirmative action policies are necessary to close gender gaps in these fields, increase representation, engagement and leadership.</p>	<p>112. Member States should adopt and enforce comprehensive policies that promote and respect gender equality and diversity in the whole lifecycle of neurotechnology. The policies should prioritize inclusive research for addressing women and their needs , require targeted data collection and analysis, include education and training programmes and inclusive research practices that ensure gender equality. Targeted policies are necessary to close gender gaps in these fields, increase representation, engagement and leadership.</p>	<p>In Bulgaria and many other countries “gender” is not a legally normative concept, normative is the biological sex. “Affirmative action” has specific connotations in US policy.</p>
<p>113. Member States should establish clear guidelines and legal frameworks to ensure that workplaces and</p>	<p>Member States should establish clear guidelines and legal frameworks to ensure</p>	<p>See comment above.</p>

<p>research environment, throughout the whole lifecycle of neurotechnology, are inclusive and supportive, particularly for women and gender minorities, and safeguard against harassment and discrimination. This should include robust mechanisms for reporting and addressing incidents of harassment and discrimination, ensuring accountability and support.</p>	<p>that workplaces and research environment, throughout the whole lifecycle of neurotechnology, are inclusive and supportive, particularly for women and safeguard against harassment and discrimination. This should include robust mechanisms for reporting and addressing incidents of harassment and discrimination, ensuring accountability and support.</p>	
<p>114. Member States should adopt a range of measures that prioritize ethical and equitable research and innovation and support programs that foster women's and gender minorities' participation in neurotechnology. This includes funding and other policies that prioritize ethical and equitable research and innovation, but also affirmative action initiatives to support the participation of women and gender minorities in neurotechnology through targeted education programs, employment opportunities, entrepreneurship support, and leadership development within the sector. Member States should also provide support systems such as mentorship programs, networking opportunities, and resources to help women and gender minorities overcome barriers to participation and succeed in the neurotechnology field.</p>		
IV.9 PERSONS WITH PHYSICAL DISABILITIES		
<p>115. Member States should adopt policies that harness the potential of neurotechnology by removing barriers experienced by persons with physical disabilities and providing support thereby contributing to achieving equal enjoyment of human rights. They should implement regulatory frameworks that require accessibility assessments for all new neurotechnology products to ensure these products do not perpetuate existing disabilities or health disparities. These frameworks should include protocols for testing with diverse groups of persons with disabilities to ensure technology meets a wide range of needs and does not unintentionally exclude or disadvantage any subgroup.</p>		

<p>116. Member States should create incentive programs to promote the development of neurotechnology for people with disabilities to promote their quality of life and functional independence. These programs should include tax incentives for companies investing in assistive neurotechnology research and development, grants for research institutions focusing on neurotechnology for disability support, expedited regulatory reviews for technologies offering significant advancements in mobility, communication, or daily living assistance, and innovation prizes for breakthroughs in affordable, accessible neurotechnology solutions.</p>	<p>Member States should create incentive programs to promote the development of neurotechnology for people with disabilities to promote their quality of life and functional independence. These programs should include tax incentives for companies investing in assistive and/or rehabilitative neurotechnology research and development, grants for research institutions focusing on neurotechnology for disability support and rehabilitation, expedited regulatory reviews for technologies offering significant advancements in mobility, communication, or daily living assistance, and innovation prizes for breakthroughs in affordable, accessible neurotechnology solutions.</p>	<p>Important to clarify that not only assistive neurotechnology should be covered.</p>
<p>117. Member States should, whenever possible, subsidise the cost of essential neurotechnology devices, such as neuroprosthetics, for persons with physical disabilities. They could encourage public-private partnerships to make advanced neurotechnology affordable and integrate neurotechnology coverage into national health insurance and other reimbursement schemes for persons with physical disabilities. A national database of available neurotechnology resources and support services should be developed to facilitate access and information sharing.</p>	<p>Member States should, whenever possible, subsidise the cost of essential neurotechnology devices, such as neuroprosthetics, for persons with physical disabilities. They could encourage public-private partnerships to make advanced neurotechnology affordable and integrate neurotechnology coverage into national health insurance and other reimbursement schemes for persons with physical disabilities. A national database of available neurotechnology resources and support services should be developed to facilitate access and information sharing. To ensure accessibility and understanding for all users, this database and related information should be available in multiple languages, allowing individuals to access critical information in their preferred language.</p>	<p>The added text in red ensures that language accessibility is presented as an integral part of making neurotechnology resources truly accessible to all potential users, regardless of their linguistic background.</p> <p>Yellow-marked section is too detailed and could be left out.</p>

IV.10 PERSONS WITH MENTAL HEALTH CONDITIONS		
118. Member States should foster research and promote awareness-raising initiatives to address the increasing prevalence and special needs of people with mental health conditions, including victims and survivors of trauma and violence, and the relevance of neurotechnology for these communities.	118. Member States should foster research and promote awareness-raising initiatives to address the increasing prevalence and special needs of people with mental health conditions, including victims and survivors of trauma and violence, and the relevance of neurotechnology for these communities .	Is communities the correct word here? Is groups of peoples be more correct or individuals suffering from these health conditions or something similar more appropriate?
119. Member States should allocate funding for long-term advocacy and efficacy studies, post- market oversight, and tiered scrutiny with special attention to invasiveness and reversibility of neurotechnology interventions. It is important to ensure that people with mental health conditions are well-informed and have reasonable expectations about the process.	Member States should allocate funding for long-term advocacy and efficacy studies, post- market oversight, and tiered scrutiny with special attention to invasiveness and reversibility of neurotechnology interventions. It is important to ensure that people People with mental health conditions are must be well-informed and have reasonable expectations about the process.	What is the essence of long-term advocacy in this context? "Defense" or "opinion/policy impact"? This paragraph is very difficult to understand and needs to be reworded.
120. Member States should prioritize funding for neurotechnology that is designed to improve quality of life and daily functioning of individuals with mental health conditions. This includes technologies that assist in managing symptoms, improving cognitive functions, and providing emotional support at home, in the workplace, in their communities, and in society. Research and development should be guided by feedback and engagement with persons with mental health conditions and their advocates.		State based funding in this context must be science based and should (as far as possible) be safeguarded from pro-profit interests.
121. Member States should establish policies that improve access to timely advances in neurotechnology for those with mental health conditions to ensure that cost is not a barrier to accessing potentially life-altering treatments and supports.		
HEALTH AND RESEARCH ETHICS		
IV.11 HEALTH		

<p>122. Member States should support the development of health applications that prioritize the unmet needs in the provision of neurological and mental health. This should include establishing research funding programs specifically targeted at addressing identified gaps in nervous system care.</p>	<p>122. Member States should support the development of health applications that prioritize the unmet medical needs in the provision of neurological and mental health. This should include establishing research funding programs specifically targeted at addressing identified gaps in nervous system care.</p>	
<p>123. Member States should build and maintain international solidarity to address global health risks and uncertainties, and ensure that their implementation of healthcare for the nervous system is consistent with international law and rigorous human rights obligations. This could involve creating international forums for sharing best practices in the implementation of neurotechnology in healthcare.</p>	<p>123. Member States should build and maintain international solidarity to address global health risks and uncertainties, and ensure that their implementation of healthcare for the nervous system is consistent with international law, medical and scientific standards, and rigorous human rights obligations. This could involve creating international forums for sharing best practices in the implementation of neurotechnology in healthcare.</p>	<p>Consider leaving out the last sentence, since it might be redundant.</p>
<p>124. Member States should establish oversight mechanisms to evaluate the physical and mental health impacts of long-term use of neurotechnological devices, with special attention to invasiveness and reversibility of neurotechnology interventions. This includes implementing regulatory measures requiring long-term follow-up studies for approved neurotechnology devices and establishing clear criteria for continued approval based on these studies results.</p>		
<p>125. Member States should consider the significant cost and impact associated with pathologies related to the nervous system, as well as the potential benefits of early diagnosis and access to preventive and assistive neurotechnology. Public policies should prioritize the promotion of access to these technologies and ensure health cost coverage for individuals in need.</p>	<p>Member States should consider the significant cost and impact associated with pathologies related to the nervous system, as well as the potential benefits of early diagnosis and access to preventive, and assistive and rehabilitative neurotechnology. Public policies should prioritize the promotion</p>	<p>Important to add rehabilitative neurotechnology.</p> <p>The implication and meaning of “[...] consider the significant cost and impact [...]” is unclear.</p>

	of access to these technologies and ensure health cost coverage for individuals in need.	
126. Member States should promote the development of reliable and durable neurotechnology for healthcare applications. This includes encouraging the design of devices and systems that require minimal maintenance, ensuring they remain functional and effective under everyday conditions. Regulatory bodies or designated authorities should oversee the enforcement of rigorous standards for quality, safety, and longevity, thereby reducing the burden on users and enhancing the dependability and sustainability of neurotechnological solutions.	126. Member States should promote the development of reliable, safe and durable neurotechnology for healthcare applications. This includes encouraging the design of devices and systems that require minimal maintenance, ensuring they remain safe , functional and effective under everyday conditions. Regulatory bodies or designated authorities should oversee the enforcement of rigorous standards for quality, safety, and longevity, thereby reducing the burden on users and enhancing the dependability and sustainability of neurotechnological solutions.	
127. Member States should ensure the development or strengthening of existing comprehensive neurotechnology medical device reporting systems that track and address adverse effects. In contexts where such systems do not exist, Member States should establish them. Where systems are already in place, they should be updated to specifically include neurotechnology. These systems should be interoperable and contribute to a centralised, public, and transparent international database, managed in collaboration with international organizations, to ensure that global standards are met and accessible for public knowledge, international oversight and research.		
IV.12 RESEARCH ETHICS		
128. Member States should reinforce the ethical frameworks governing neurotechnology research to ensure robust protection of human participants. Member States should adopt clear guidelines or policies that define the qualifications to ensure that research is conducted by professionals with appropriate knowledge	[...] Furthermore, research protocols, public or private, in the medical as well as the non-medical domain, should be carefully evaluated by registered ethics boards (ethics committees) and specific attention dedicated to individuals with special situations	The requirements of “[...] specific attention dedicated to individuals with special situations regarding vulnerability such as diminished capacity to consent or to make decisions [...]” is vague in comparison to established medical ethics,

<p>about the nervous system structure and function in addition to brain disorders and is performed in adequate research settings. Furthermore, research protocols, public or private, in the medical as well as the non-medical domain, should be carefully evaluated by registered ethics boards (ethics committees) and specific attention dedicated to individuals with special situations regarding vulnerability such as diminished capacity to consent or to make decisions. Member States should ensure that all research institutions have mandatory ethics training for researchers.</p>	<p>regarding vulnerability such as diminished capacity to consent or to make decisions. [...]</p>	<p>which require that research is not performed on people with diminished capacity to consent/dissent if it can be performed on people with full capacity to do so.</p> <p>Consequently, the text must be reworded to stay in line with established medical and research ethical standards.</p>
<p>129. Member States should encourage multicentre international research that involves various cultures and ethnic groups. Member States should promote international cooperation to develop common reporting standards and protocols for interoperability, particularly for implantable neurotechnology devices. This cooperation should aim to enhance the comparability and utility of research globally, improving both the efficacy and ethical integrity of research.</p>		
<p>130. Member States should ensure that the whole lifecycle of neurotechnology is considered in the design of a clinical trial, including policies to protect patients in case of cessation of activities of the trial sponsor or promoter. Member States should establish requirements for clinical trials to be included in relevant nationally or internationally approved registries and encourage registration with community and patient registries. Also, clinical trials should report on appropriate medical device reporting systems developed within Member States.</p>		<p>As in §46, the document fails to support the rights of trial patients to continued treatment after the end of the trial.</p>
<p>131. Technology developers should ensure that the validation of AI algorithms in neurotechnology research include rigorous testing for biases, as well as measures to enhance explainability and transparency, including the provenance of training datasets. Suitable techniques</p>		<p>Maybe it would it be more feasible to address AI in a separate section/chapter? This paragraph is applicable for other areas besides health.</p>

<p>should be employed to mitigate any biases present in AI models used in neurotechnology applications.</p>		
<p>132. Member States should ensure that research efforts not only focus on biomedical risks associated with neurotechnology but also investigate potential effects on an individual's subjective experience, agency and personal identity. Understanding how neurotechnology may impact aspects of self-perception, consciousness, and identity is essential for addressing ethical concerns and ensuring the well-being of individuals using these technologies.</p>		<p>This paragraph presumes that issues concerning the patient's "[...] subjective experience, agency and personal identity" are not part of "biomedical" assessments. These issues are essential parts of any competent clinical assessment of a patient's health and well-being.</p>
<p>133. Member States should ensure those engaged in research implement regular auditing and monitoring of research practices to ensure adherence to ethical standards. This should include evaluating the adequacy of informed consent, particularly concerning data reuse and the potential commercialisation of neural data.</p>		
<p>134. Member States should require researchers in neurotechnology to establish clear and transparent protocols for communicating clinically significant and actionable incidental findings to participants. These protocols should ensure that such findings are conveyed promptly, respecting participants' rights and autonomy. Additionally, Member States should mandate that researchers provide the necessary support and coordination with healthcare providers to address any health concerns that arise from these findings.</p>		
<p>135. Member States should ensure that individuals involved in neurotechnology research or receiving neurotechnological interventions are adequately informed about the potential for incidental findings, particularly those with significant health implications. The informed consent process should clearly outline what these findings might entail, the participants' right to choose whether they wish to be informed about such findings, and guarantee that their decisions in this</p>		

regard will be respected throughout the study or treatment.		
SPECIFIC DOMAINS OF APPLICATION OUTSIDE OF HEALTH		
IV.13 EDUCATIONAL SETTINGS		Are the recommendations applicable to all educational settings or would references to specific educational settings improve the feasibility?
136. Member States should approach with caution the integration of neurotechnology in education, ensuring that its use is evidence-based and aligned with the education goals and complements traditional learning methods. Emphasis should be placed on promoting the holistic development of students, focusing not just on academic performance but also on mental health, well-being, and overall interests. To ensure inclusivity, Member States should develop age- appropriate guidelines for neurotechnology use across different educational stages and learning styles. Regular assessments of neurotechnology's impact on student development, including mental health, should be conducted, with ethical review processes established to oversee deployment. The primary focus should be on fostering critical thinking, creativity, and emotional intelligence rather than solely enhancing academic performance.		
137. Member States should adopt policies ensuring the voluntary deployment of neurotechnology in education, grounded in fully informed consent. These policies must include clear, age- appropriate information about the technology's purpose, benefits, and risks, with adequate consideration periods. Considering the increased complexity of obtaining voluntary consent in this context, consent and assent procedures should involve children, adolescents, parents, guardians and all actors necessary to obtain approval required for minors. Ethical oversight mechanisms should be established,	Member States should adopt policies ensuring that the voluntary deployment of neurotechnology in education are grounded in fully informed consent. These policies must include clear, age- appropriate information about the technology's purpose, benefits, and risks, with adequate consideration periods. Considering the increased complexity of obtaining voluntary consent in this context, consent and assent procedures should involve children,	Long paragraph, should be split up.

<p>including regular consent renewal and immediate cessation of neurotechnology use upon withdrawal, and ensure anonymous feedback channels. Policies must prohibit undue incentives or academic penalties for non-participation and take measures to avoid creating or reinforcing inequalities among students. Additionally, Member States should support student involvement in decision-making about neurotechnology integration and fund training programs on its ethical use, empowering educators and students to critically assess its application.</p>	<p>adolescents, parents, guardians and all actors necessary to obtain approval required for minors.</p> <p>---</p> <p>Ethical oversight mechanisms should be established, including regular consent renewal and immediate cessation of neurotechnology use upon withdrawal, and ensure anonymous feedback channels. Policies must prohibit undue incentives or academic penalties for non-participation and take measures to avoid creating or reinforcing inequalities among students.</p> <p>---</p> <p>Additionally, Member States should support student involvement in decision-making about neurotechnology integration and fund training programs on its ethical use, empowering educators and students to critically assess its application.</p>	
<p>138. Member States should establish a unified, robust oversight mechanism for neurotechnology use in educational settings, incorporating regular audits, public and community feedback, culturally appropriate and according to local conventions, and strict adherence to safety and ethical standards, including an assessment of reversibility on the nervous system. Continuous research should be funded to assess the long-term psychological and cognitive impacts of these technologies. Oversight should involve periodic reviews based on empirical evidence to adjust neurotechnology usage as needed, ensuring it serves student development and addresses risks like dependency or de-skilling. This comprehensive approach will help maintain the safety, effectiveness, and alignment of neurotechnology with best practices for student well-being and learning outcomes.</p>	<p>Member States should establish a unified, robust oversight mechanism for neurotechnology use in educational settings at all levels of education, incorporating regular audits, public and community feedback, culturally appropriate and according to local conventions, and strict adherence to safety and ethical standards, including an assessment of reversibility on the nervous system.</p> <p>----</p> <p>Continuous research should be funded to assess the short- and long-term psychological and cognitive impacts of these technologies. Oversight should involve periodic reviews based on empirical evidence to adjust neurotechnology usage</p>	<p>Long paragraph, should be split up.</p> <p>Consider giving examples of these technologies. Also see §55.</p>

	as needed, ensuring it serves student development and addresses risks like dependency or de-skilling. This comprehensive approach will help maintain the safety, effectiveness, and alignment of neurotechnology with best practices for student well-being and learning outcomes.	
139. Member States should invest in educational and professional development programs to equip innovators and business leaders with the skills to integrate ethical considerations throughout the neurotechnology whole lifecycle. This training should include ethical design, human rights law, and societal impact assessment, preparing the next generation of technologists to critically evaluate the implications of their work.		Questionable to make the state responsible for this type of capacity development for the business sector. If this paragraph will remain, also consider moving it. Capacity building in the private sector could also be under IV.14 LABOUR AND EMPLOYMENT .
IV.14 LABOUR AND EMPLOYMENT		The responsibilities of the employers should be emphasized. This section is very long, should benefit from being shortened.
140. Member States should establish workplace policies and incentives that prioritize the health and well-being of employees in the use of neurotechnology. These policies should ensure that any deployment of neurotechnology is evidence-based, with a focus on applications that have been scientifically validated to promote employee well-being, such as reducing stress or enhancing workplace conditions (i.e., adaptive and responsive environments that adjust workloads based on cognitive load). Deployment must be on a voluntary basis and employees must have the option to opt out of using neurotechnology without facing any negative consequences or discrimination. Under no circumstances should these technologies be used for punitive measures, mental surveillance, or in ways that could compromise employee health.	140. Member States should establish policies and laws regarding the use of neurotechnology in the workplace to safeguard the privacy and safety of the employees. workplace policies and incentives that prioritize the health and well-being of employees in the use of neurotechnology. These policies should ensure that any deployment of neurotechnology is evidence-based, with a focus on applications that have been scientifically validated to promote employee well-being, such as reducing stress or enhancing workplace conditions (i.e., adaptive and responsive environments that adjust workloads based on cognitive load). ----	Consider splitting the paragraph here.

	Deployment must be on a voluntary basis and employees must have the option to opt out of using neurotechnology without facing any negative consequences or discrimination. Under no circumstances should these technologies be used for punitive measures, mental surveillance, or in ways that could compromise employee health.	
141. Member States should require employers to clearly provide employees with comprehensive information about how neurotechnology used in their workplace works, the benefits it offers, transparency about what data are collected, how it is used, and who has access to it, and clearly disclose any potential risks of their use.		
142. Member States should require employers who use neurotechnology in the workplace to adopt transparent policies that disclose the purpose of the use, limit the scope of its use to legitimate purposes in the interest of the employee and third parties (i.e., safety, monitoring fatigue in commercial drivers or tracking attention in air traffic controllers). To respect employees' mental privacy, employers should be prohibited from unauthorized access to neural and cognitive biometric data that may be collected incidentally during routine workplace monitoring. Employers should be prohibited from using neural and cognitive biometric data for any non-consented purposes, particularly those that could negatively impact an employee's job security or privacy.		
143. Member States should require employers to adopt best practices for data minimisation and secure storage of neural and cognitive biometric data, ensure that data is stored securely, with access limited to authorised personnel only, is deleted once its intended purpose has been fulfilled. Additionally, upon an employee's departure, all related records should be fully deleted or		

<p>individual data released to the employee, ensuring that no data is retained after the termination of employment.</p>		
<p>144. Member States should ensure that when employees are issued multifunctional devices (i.e., earbuds or headphones that also include neural sensors) that can be used at work or at home, employers should be prohibited from collecting neural and cognitive biometric data outside of workplace settings and working hours and ensure that any data collected during work is used exclusively for agreed-upon purposes. Employers should implement technological safeguards to automatically disable data collection during non-work hours.</p>		<p>Re-write this paragraph in order to make this recommendation applicable also for other types of devices, unless it is relevant to highlight these devices specifically.</p> <p>Moreover, Member States should ensure that during work, only minimal and necessary data is collected for the exclusive use for agreed-upon purposes.</p>
<p>145. Members States should ensure that employers respect the right of employees to obtain a copy of any neural and cognitive biometric data collected about them, along with any interpretations drawn from it in an accessible and comprehensible manner. To use these tools without consent constitutes a breach of trust, undermining the value they would otherwise create.</p>		
<p>146. Member States should require, through stringent regulations, that any use of neurotechnology in the workplace require explicit employee consent, and be used only for purposes that demonstrably enhance workplace safety, employee well-being and dignity, and not for enhancing productivity at the expense of employee health.</p>		
<p>147. Member States should guard against the exploitation of employees, and they should develop stringent regulations against using neural and cognitive biometric data for profiling in the workplace, including in hiring. These regulations should prohibit the use of neural and cognitive biometric data to discriminate against candidates, particularly neurodiverse</p>		

individuals, ensuring hiring practices are fair and inclusive.		
148. Member States should strictly regulate the use of neurotechnology for hiring or maintaining employment, to limit such use where such neural and cognitive biometric data are directly relevant to the specific requirements of the job.		
IV. 15 CONSUMER AND COMMERCIAL DOMAINS		
149. Member States should proactively establish a regulatory framework that balances innovation in the recreational and commercial domains with protecting individual rights and well-being. This framework should be dynamic, allowing for timely updates as technology evolves and new insights are gained about its impacts on society. This includes providing adequate oversight to ensure that neurotechnology does not cause harm, are used consensually, and include robust mechanisms to protect users from potential psychological distress or manipulation.		We are afraid that this is too vague to ensure that the recreational and commercial industries respect individual rights etc. since their whole business idea is to profit on people's desire to boost their health and well-being.
150. Member States should strengthen comprehensive consumer protection laws to include clear labelling on commercial neurotechnology products, detailing their effects, limitations, and risks to prevent misleading claims and ensure transparency. This also includes prohibiting practices of "tying" or requiring the disclosure of neural and cognitive biometric data as a condition to access goods or services, and prohibition about third party data sharing or the uses of this data without affirmative opt-in option.		
151. Member States should foster an environment that ensures all claims about consumer, non- medical technologies are supported by robust scientific evidence. They should, by regulation, require that any products claiming to treat, prevent, or diagnose		

diseases or medical conditions be validated through rigorous safety and efficacy testing, including clinical trials where necessary, and be used under appropriate medical supervision.		
152. Member States must enforce informed consent processes that are thorough and transparent across all neurotechnological interventions, ensuring that participation is fully voluntary and respects the privacy and autonomy of individuals. This principle should apply uniformly in various domains such as sports, arts, where robust standards should safeguard against coercive use and respect athletes' and artists' individual autonomy, community interests, and IP rights.	Member States must enforce informed consent processes that are thorough and transparent across all neurotechnological interventions, ensuring that participation is fully voluntary and respects the privacy and autonomy of individuals. This principle should apply uniformly in various all domains such as sports, arts, where robust standards should safeguard against coercive use and respect athletes' and artists' individual autonomy, community interests, and IP rights.	Are there good reasons for addressing sports and arts specifically?
153. Member States should steer the use and development of neurotechnology in the arts toward ensuring the enhanced learning and cultural appreciation without compromising individual autonomy or leading to cultural homogenisation.		The message here is unclear. Does neurotechnology have the potential to enhance cultural appreciation? Member States should definitely not intervene on people's cultural experiences.
154. Member States should adopt policies to prevent the misuse of neurotechnology of consumer technology, especially neurogaming and other devices that exploit the dopamine reward system or seek to induce problematic and unhealthy use and overconsumption. Such regulations should mandate clear labeling of risks, disclosures on their effects on the nervous system, enforce game design standards and safety, privacy and age-appropriate design standards that prevent taking advantage of a person's physical, mental and emotional vulnerability to lead to compulsive use or addiction of gaming or digital recreational platforms combined with neurotechnology, to promote healthy, balanced use, especially among children.		adopt policies too vague? And what are the Tech companies' responsibilities?

<p>155. Member States should ensure that devices capable of multiple functions, such as XR glasses or smart earbuds with neural sensors, include hardware-based controls that allow users to selectively disable neurotechnology features while maintaining basic functionality. Regulations should ensure that 'opt-out' features are accessible and straightforward, promoting healthy, balanced use especially among children and vulnerable populations.</p>		<p>Should management and ownership over data generated through the use of these devices be mentioned? Or is this taken care of in the section of Data Policy? If yes, maybe a good idea to refer to that section?</p>
<p>156. Member States should address the profound ethical questions regarding self-determination, consent, privacy, and the potential for manipulation raised by neurotechnology that arise in the contexts of recommender systems, priming and nudging, marketing during sleep and dream, neuromarketing, and closed-loop environments by adopting comprehensive policies and regulations that:</p>		<p>Subliminal messaging should also be included. Is this the same term?</p>
<p>(a) Recommender systems: explicitly prohibit the use of neural and cognitive biometric data in recommender systems for manipulative or deceptive purposes, including in political context. These regulations should require that any use of such data within these systems be based on explicit, informed opt-in consent from users.</p>		
<p>(b) Nudging: govern the use of neural and cognitive biometric data for nudging-subtly influencing individuals' decisions or behaviours, often without their explicit awareness. This is</p>		

<p>particularly critical in sensitive areas such as political messaging, commercial advertisement, and healthcare. These frameworks should require explicit, informed consent for any use of such data to influence decisions or behaviour, the right to opt out of these systems, and transparency and clear disclosures at the point of data collection, with strict limitations on using data for purposes beyond those explicitly disclosed.</p>		
<p>(c) Marketing during sleep and dream: prohibit the use of neurotechnology that influences or manipulates individuals during sleep, such as marketing during sleep and dream. Regulations should strictly prohibit commercial, marketing, or political applications that target individuals during sleep, using neurotechnology or neural and cognitive biometric data. Additionally, robust oversight mechanisms should be required to ensure that any research or application of such technologies prioritizes the well-being, privacy, and autonomy of individuals, with particular attention to the potential long-term psychological and cognitive impacts of manipulating sleep states.</p>		

<p>(d) Neuromarketing: safeguard against unethical aims and practices in neuromarketing, including by requiring comprehensive disclosures to ensure that all neuromarketing activities are conducted transparently, with participants' explicit informed consent. This includes ensuring that participants in neuromarketing research or campaigns are fully aware of methods, risks, and intentions and affirmatively opt-in to participation. The use, storage, and potential reuse of the collected data should be strictly regulated.</p>		
<p>(e) Closed Loop Environments: provide clear regulatory guidelines on the design and use of closed-loop environments-such as immersive computing devices that adjust experiences based on detected neural and cognitive biometric data. These policies should require clear and accessible disclosure about how neural and cognitive biometric data are used in these environments, prohibit real-time behavioral modification or manipulation without explicit, informed consent, and implement safeguards specifically designed to prevent abuses such as unauthorized surveillance, manipulative interventions, and practices that could influence voting</p>		

<p>behavior, political opinions, or exploit psychological and emotional vulnerabilities in real-time.</p>		
<p>IV.16 ENHANCEMENT</p>		<p>This section should be given more attention.</p> <p>The implications of neurotechnological enhancement, especially when innovations extend beyond therapeutic applications within healthcare and move into areas of human enhancement, require particular attention. As new neurotechnological innovation emerge, there is a growing potential for their application in enhancing human cognition and abilities outside traditional medical contexts, raising important ethical and social considerations. In reviewing the draft of this Recommendation, we note that while the document addresses various ethical aspects of neurotechnology, there is limited exploration of enhancement applications of new neurotechnological innovations. Considering the profound implications of such applications, we would encourage a more comprehensive analysis of this topic within the recommendations. It is crucial that the risks and responsibilities associated with human enhancement technologies are further considered in order to ensure that ethical principles and appropriate legislation are robustly applied in this emerging area.</p>
<p>157. The use of neurotechnology to improve memory, attention, or other aspects of human mental performance outside of the medical context introduces complex</p>	<p>The use of neurotechnology to improve memory, attention, or other aspects of human mental performance outside of the medical</p>	<p>The phrase outside of the medical context is difficult to interpret, particularly since enhancement of the nervous system itself</p>

<p>ethical, social, and legal challenges, which can create new kinds of disparities in the global world. When neurotechnology is used in these contexts, it raises crucial questions about equity, consent, individual and community autonomy, and the nature of enhancement of the nervous system itself. Member States should ensure that any policies, law and regulatory frameworks that govern the use of neurotechnology in these contexts do not exacerbate social inequalities or lead to discrimination, address the potential risks (including to reversibility, invasiveness, and risks to self-determination) and fully comply with human rights and dignity.</p>	<p>context introduces complex ethical, social, and legal challenges [...] When neurotechnology is used in these contexts, it raises crucial questions about equity, consent, individual and community autonomy, and the nature of enhancement of the nervous system itself. [...]</p>	<p>is included. The principle of non-maleficence in medical ethics should be an important part of the ethics of neurotechnology and other applied neuroscience.</p>
<p>V. IMPLEMENTATION</p>		
<p>158. Member States and all other actors as identified in this Recommendation should respect, promote and protect the ethical values, principles and standards related to this Recommendation, and should take all feasible steps to give effect to its implementation.</p>		
<p>159. Member States shall, according to their specific contexts, governing structures and constitutional provisions, credibly and transparently advance the ethics of neurotechnology, in line with the UNESCO Recommendation. Member States shall monitor and evaluate policies, programmes and mechanisms related to neurotechnology and its ethics. Progress monitoring could rely on a combination of quantitative and qualitative approaches.</p>		
<p>160. Member States should develop capacities in governmental institutions and support government officials to steer the technological development ethically.</p>		
<p>161. Member States should establish or designate national organizations responsible for overseeing and</p>		

<p>coordinating the regulation, vigilance, and oversight of neurotechnology across relevant government agencies. These coordinating bodies should be tasked with ensuring that legal and regulatory frameworks are consistently applied, that public health and safety are protected, and that ethical standards and human rights are upheld throughout the whole lifecycle of neurotechnology. This includes facilitating inter-agency collaboration, monitoring compliance with national and international standards, and ensuring that data and insights from different regulatory domains are shared effectively to inform decision-making and policy development. These bodies should also help coordinate public and community engagement.</p>		
<p>162. Member States should strive to extend and complement their own actions in respect of this Recommendation, by cooperating with all relevant national and international governmental and non-governmental organizations, as well as transnational corporations and scientific organizations, whose activities fall within the scope and objectives of this Recommendation. Civil society will be an important actor to advocate for the public sector's interests and therefore UNESCO needs to ensure and promote its legitimacy.</p>		
<p>163. UNESCO should publicize and disseminate this Recommendation widely through all available means, and share it with Member States, National Commissions for UNESCO, relevant international and regional partners, human rights institutions as well as with UNESCO ethics advisory bodies for dissemination to all levels and actors in this field.</p>		
<p>164. To support Member States implementing this Recommendation by developing concrete programs and policies and developing institutional capacities in the ethics of neurotechnology, UNESCO shall</p>		<p>Compare VII. Promotion of the present Recommendation, §137-139 in the Recommendation on the Ethics of Artificial Intelligence (2021). For this</p>

<p>contribute by developing a full-fledged program with the following elements:</p>		<p>Recommendation to be relevant for many years to come, it might be a good idea to outline guidelines rather than a list of concrete initiatives.</p>
<p>(a) UNESCO Readiness Assessment Methodology (RAM) to assist Member States in identifying their status at specific moments of their readiness trajectory along a continuum of dimensions;</p>		
<p>(b) UNESCO methodology for Ethical Impact Assessment (EIA) of neurotechnology based on rigorous scientific research and grounded in international human rights law, along with specific guidance for its implementation in the whole neurotechnology lifecycle, and capacity-building tools and materials to support Member States' efforts to train government officials, policy-makers and other relevant actors on the methodology;</p>		
<p>(c) UNESCO methodology to evaluate ex ante and ex post the effectiveness and the efficiency of the policies for the ethics of neurotechnology and incentives against defined objectives;</p>		
<p>(d) UNESCO research program that will focus an the ethics of neurotechnology, grounded on an appraisal that is informed by the current state of technological developments, to assess the current and future impact of neurotechnology an societies and the environment. This evidence-based analysis will be gathered in a UNESCO observatory, to become a shared pool of knowledge and awareness of good practices and innovations available to all Member States and actors, in the form of research reports, data, and statistics regarding policies for ethics of neurotechnology. The research program should take into consideration the converging developments of neurotechnology with other technologies such as artificial intelligence and quantum</p>		

technology, work to be conducted in collaboration with other relevant UNESCO initiatives.		
(e) UNESCO collaborative platform fostering meaningful exchanges and facilitating collaboration among Member States and among all actors to promote a global policy dialogue, including at Ministerial level in the context of a Global Forum on the ethics of Emerging Technologies. Supporting this effort, UNESCO shall establish a network of experts, with balanced representation of all UNESCO's regional groups, on the neurotechnology.		
165. Processes for monitoring and evaluation should ensure broad participation of all actors, including, but not limited to, under-represented, vulnerable people or people in vulnerable situations and ensuring social, cultural and gender diversity. The monitoring and assessment of the impact of neurotechnology and related ethics policies and practices should be carried out continuously in a systematic way proportionate to the relevant risks. This should be based on internationally agreed frameworks and involve evaluations of private and public institutions. Data collection and processing should be conducted in accordance with international law, national legislation on data protection and data privacy, and the values and principles outlined in this Recommendation.		
VI. FINAL PROVISIONS		
166. This Recommendation needs to be understood as a whole, and the foundational values and principles are to be understood as complementary and interrelated.		
167. Nothing in this Recommendation may be interpreted as replacing, altering or otherwise prejudicing Member States' obligations or rights under international law, or as approval for any State, other		

political, economic or social actor, group or person to engage in any activity or perform any act contrary to human rights, fundamental freedoms, human dignity and concern for the environment and ecosystems.		
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