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**CONSULTATIVE COMMITTEE OF THE CONVENTION
FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO
AUTOMATIC PROCESSING OF PERSONAL DATA**

(CONVENTION 108)

**Draft Guidelines on Data Protection in the context of neuroscience and
neurotechnologies**

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to be drafted as a final step

Introduction¹

1. The rapid advancement of neurotechnologies has introduced unprecedented opportunities for understanding, monitoring, and modulating human brain activity. It enables at the same time to access, investigate, evaluate, manipulate, and/or emulate such activities of the human brain. Neurotechnologies encompass a broad spectrum of tools and systems, from brain-computer interfaces (BCIs) and neural implants to neuroimaging and neuromodulation techniques. These technologies hold transformative potential for science, medicine, clinical care, rehabilitation and improvement of [health/] and well-being. However, they also raise profound/complex] ethical, legal, and societal challenges², particularly regarding the potential impact of the processing (collection, storage, etc.) of neural data, on the most private and intimate sphere of the individuals whose data are processed.
2. In particular, the processing of such data offers great promise for advancing neuroscience medicine and healthcare, including in the understanding of the human brain, the nervous system as well as in the diagnosis and treatment of neurological and psychiatric disorders. At the same time, it [may] poses particularly significant risks/cause significant harm] to human rights, rule of law and democracy, including through unlawful interference with individuals' privacy, breaches of data protection laws, state or commercial surveillance, or manipulative, disruptive or deceptive uses and practices. Such [risks/concerns] should be addressed as early as possible, at the highest international level through appropriate policy making and regulatory processes and subsequently active and effective international cooperation, including on enforcement.
3. Moreover, regulators and stake holders need to closely observe the significant distinction in terms of potential harms to those values when neural data is processed in the framework of medical versus non-medical use of neurotechnology, and the distinction between its use as treatment or with the aim of enhancement³. Based on this distinction they need to establish and comply with stricter standards and rules outside of the medical, healthcare and scientific research fields, thereby out of applicable specific legal and ethical standards, as the development and application of neurotechnology outside of these areas are susceptible to lead to profound transformations in the reasonable expectation of privacy by individuals or the exercises of the right to informational self-determination and other human rights and fundamental

¹ All concepts referred to in the Introduction should be interpreted according to the definitions provided later in the text and the provisions of Convention 108+ and its Explanatory Report

² Those terms should be understood as the well-established concept of Ethical, Legal and Societal Implications (ELSI), which has been widely used in the governance of emerging technologies since the Human Genome Project and is now commonly applied to AI and neurotechnology. In the context of these Guidelines, this encompasses the implications of neural data processing for human rights, human dignity, personal autonomy, privacy, principle of non-discrimination, accountability, public trust, and broader societal impacts.

³ In line with UNESCO's Recommendation on the Ethics of Neurotechnology

freedoms. As such it has a potential of disrupting individuals' private life and the society as a whole. It is crucial therefore that such standards and rules consider appropriate legal and ethical considerations in a broader sense so that neurotechnologies are only conceived and used in ways that benefit all individuals inclusively and democratic societies. Any unlawful interference with mental privacy or the manipulation or alteration of mental integrity and ultimately any attempt to harm or negatively affect human dignity must be strictly prevented/prohibited. Neurotechnologies process neural data, i.e. data derived from the human nervous system, including neurophysiological activity, neuroanatomical images and signals or patterns associated with brain and nervous system functioning. Such data constitute personal data whenever [they contain information relating to an identified or identifiable individual (data subject)], also in cases where identification or re-identification would not require unreasonable time, effort or resources, including through combination with other datasets or analytical techniques.

4. Neural data have a highly sensitive connotation due their origin in the human nervous system and its potential to reveal particularly intimate aspects of an individual's cognitive or neurological states, mental health, behaviour, thoughts, beliefs, emotions, origins or identity.
5. As such, neural data may often qualify as health-related data (including mental health) or data that reveals other protected areas of an individual's private life (racial, ethnic origins, opinions, beliefs, thoughts, political affiliation, sexual life, etc.) under Article 6 of the Protocol CETS No 223 amending Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data (ETS No 108); ("Convention 108+)"⁴.
6. [Moreover, when allowing the unique identification of a person, neural data would constitute a permanent form of biometric data. In cases however where a person may only be indirectly identified e.g. on the basis of contextual data, neural data should not be assimilated with biometric data. Neural data generally does not qualify as genetic data as they don't relate to the genetic characteristics of an individual which have been either inherited or acquired during early prenatal development. They might qualify as genetic data nevertheless if they were obtained from the concerned individual as a result from an analysis of a biological sample which is or contain neural data: chromosomal, DNA or RNA analysis or analysis of any other element enabling equivalent information to be obtained.]
7. Therefore, in line with relevant provisions of Convention 108+, the enhanced, additional protection applicable to special categories of data under Article 6 of Convention 108+ should extend to neural data. [as without prejudice to/including prohibitions of processing in breach of human dignity or other fundamental rights. / When the level of protection afforded by Article 6 cannot be reasonably secured the processing of such data should not be authorized].
8. Against this background, it is crucial to ensure the strict application and effective enforcement of Convention 108+, and the adoption of additional safeguards enshrined in law, as provided by Article 6, that are specifically tailored to the sensitivity and potential impact of neural data processing in different contexts as detailed above.

⁴ Such approach is informed by Paragraph 58 of the Explanatory Report: "Specific types of data processing may entail a particular risk for data subjects independently of the context of the processing."

9. Neurotechnologies should aim at the well-being of individuals and societies and never be used in ways that may violate the dignity or rights of any individual, including cognitive freedom, mental privacy, integrity and personal autonomy⁵. In line therefore with the human rights-based approach of the Council of Europe, the application of neurotechnologies for development, research, and public health should also comply with applicable rules⁶. In terms of data protection guarantees and safeguards only exceptions that pursue legitimate aims, respect the essence of fundamental rights and are necessary and proportionate in a democratic society can be allowed.⁷ Furthermore, it seems to be of high importance to incorporate appropriate legal, technical and organizational safeguards to ensure the protection of the rights and freedoms of the data subjects throughout the lifecycle of the use of neurotechnology in these fields, including through data protection by design and by default. Special attention should be paid to preventing discriminatory, coercive, manipulative, or exploitative uses of personal data, especially in contexts characterized by power imbalances or vulnerability such as the new forms of vulnerabilities revealed by neurotechnology.
10. Because of the inherently sensitive nature of neural data, which in the absence of appropriate safeguards is susceptible to lead to serious discriminatory practices or other infringements of human rights, it is crucial to ensure the reaffirmation and effective enforcement of human rights and data protections frameworks, including through international cooperation, notably based on article 17 of Convention 108+ to address the unprecedented challenges posed by neural data in the digital age worldwide.

Overview of the main guarantees and safeguards

1. The Council of Europe Convention for the Protection of Individuals with Regard to the Automatic Processing of Personal Data (ETS. No 108, "Convention 108") and Convention 108+, safeguard the right to privacy and to the protection of personal data. These instruments establish binding principles and rules applicable to all processing of personal data, including the principles of lawfulness, fairness, transparency, purpose limitation, necessity and proportionality, data minimization, accuracy and data quality, storage limitation, integrity and confidentiality, accountability, and the requirement that processing pursue legitimate aims. They also require that appropriate safeguards be implemented to protect individuals against unlawful or arbitrary interferences with their rights and freedoms. In accordance with the principles enshrined in "Convention 108+", the processing of neural data must respect human dignity, human rights and fundamental freedoms, in particular the right to private life and the right to the protection of personal data. The development and deployment of neurotechnologies should therefore incorporate appropriate

⁵ As highlighted by the UN Special Rapporteur on the right to privacy "The development and use of neurotechnologies must help to uphold the right of every person to a dignified life. It should be ensured that the benefits of scientific and technological progress serve to respect and protect fundamental rights, such as the rights to identity, autonomy, privacy and the free development of personality ».Quote Unesco Recommendation

⁶ Oviedo convention, etc

⁷ Guidelines on A11

legal, technical, and organizational safeguards, including data protection by design and by default, throughout the entire lifecycle of processing activities. Convention 108+ provides principles for strengthened security, including in digital and cyber environments, to prevent unauthorized access, use, disclosure, misuse, alteration or loss of personal data. These principles need to be interpreted rigorously and lead to the adoption of particularly robust measures in light of complex and evolving technological contexts, such as neuroscience and neurotechnology, and the special risks for individuals that may derive from the processing of neural data

2. Against this background, it should be noted that the unique characteristics of neural data require additional interpretative and normative efforts to adapt existing data protection principles to neurotechnological applications.
3. [These Guidelines therefore propose practical modalities for applying the principles enshrined in Convention 108 and Convention 108+ to neural data and the processing of neural personal data in the context of neurotechnologies, with a view to ensuring / It has to be ensured] that the rights to privacy and data protection remain appropriately safeguarded and guaranteed in line with international standards.
4. [These Guidelines reflect/While using those technologies, stakeholders need to take into account] the realities of the digital age and address novel challenges associated with neural data processing, including the lack of specific and comprehensive legal frameworks at both international and domestic levels, the risk of re-identification of data subjects from seemingly anonymized neural data, the need to ensure that processing is based on a valid legitimate basis and pursue legitimate purposes, and the need to ensure the strict and effective application of the purpose limitation principle in neurotechnological contexts.
5. Regulatory attention should not exclusively focus on neural data as such, but also on the inferences that may be derived from such data, whether in isolation or in combination with other datasets (including behavioral, biometric, social media or contextual data). Many of these inferences are increasingly generated through artificial intelligence (AI) systems applied to neural data. While such systems may support legitimate scientific, clinical, assistive, or research purposes, they may also increase the risks of profiling, discrimination, manipulation, erroneous predictions, and intrusions into mental privacy. Accordingly, the safeguards and guarantees provided by Convention 108+ apply not only to the collection of neural data, but also to AI-enabled processing, inference generation, and decision-making based on such data.
6. Certain categories of inferences may pose heightened risks to data subjects' mental privacy, personal autonomy and non-discrimination and therefore require the most rigorous application of the safeguards and guarantees provided by Convention 108+, including: (i) decoding of visual or semantic content from brain activity; (ii) emotion recognition or affective state detection; (iii) predictive information relating to neurological or psychiatric conditions; and (iv) predictive inferences about intentions, preferences or future behavior .
7. In addition to the undue inferences that neurotechnology may affect a person's privacy, the processing of neural data for cognitive enhancement and/or to influence the formation of an individual's will or an aspect of his personality, thereby altering its natural development should only be authorised for medical treatment under strict conditions and where appropriate data protection

guarantees and safeguards have been laid down by law in line with Convention 108+.

8. The specific characteristics of neural data — including the possibility of inferring subconscious or highly intimate information, the risk of re-identification from seemingly anonymized datasets, and the emergence of behavioral profiling — pose additional challenges for ensuring that data subjects remain in control of their data and continue to enjoy meaningful informational self-determination requiring additional safeguards consistent with Convention 108+.
9. An interpretation of the provisions of Convention 108+ has to be tailored to neural data processing, notably requirements relating to the appropriate [legitimate/lawful] basis and legitimate purposes for the processing, the principles of necessity and proportionality, purpose limitation, transparency, accountability and security should be established. They also recommend anticipatory risk assessment in light of evolving technological capabilities and provide guidance on the implementation of appropriate safeguards, and guarantees under the Convention, including technical and organizational measures, independent oversight mechanisms, effective remedies, lawful limited exceptions, and other legal and procedural protections necessary to safeguard the rights and freedoms of data subjects.
10. It is of high importance to give practical recommendations for the processing of neural data by recommending the adoption of appropriate safeguards for the rights and freedoms of the data subject that has an essential role in safeguarding mental privacy and cognitive integrity, as outlined in Article 6 of Convention 108+ and supported by several domestic legislations in the Parties.
11. The Guidelines also address broader concerns associated with neural data, including the correlation between brain activity and user preferences, behaviors, and identities. These risks are particularly pronounced in scenarios involving unauthorized data collection, sharing, or analysis, where statistically significant associations or re-identification risks emerge from otherwise de-identified data. Article 1 of Convention 108+ underscores the importance of addressing such risks first and foremost to consider the private life of individuals in a large sense therefore always adhere notably to fair and transparent data processing practices, the use of purpose limitation principle, strong security measures, and appropriate oversight mechanisms.
12. The Guidelines contain a list of relevant definitions and three chapters of main, high level, yet practical recommendations. By providing general recommendations (section I) and then addressing to the main categories of actors (i.e. policy makers and supervisory authorities in section II; developers, manufacturers and service providers, in section III) that are facing a unique challenge posed by neurotechnologies when creating an ecosystem for such new technology, these Guidelines aim to ensure that neural data processing is conducted in a manner that respects the principles of human rights, rule of law and democracy; secure mental privacy, and mental integrity and promotes responsible innovation in neuroscience.
13. Nothing in the present Guidelines shall be interpreted as precluding or limiting the provisions of the European Convention on Human Rights and of Convention 108 and Convention 108+.

14. These guidelines should be read in conjunction with other relevant Council of Europe documents and recommendations.⁸

Definitions

For the purposes of this recommendation all definitions used in the Guidelines shall be interpreted in accordance with the provisions of the Convention 108+ and the documents on Interpretation of its provisions elaborated by the Committee.

The expression "**neural data**" refers to all personal data derived from the brain or nervous system of an individual. This includes, but is not limited to, data obtained through neuroimaging, brain-computer interfaces (BCIs), neurostimulation devices, electrophysiological recordings, and other neurotechnological tools. Neural data, *inter alia* and taking into account other data or meta data, reveal cognitive, emotional, or behavioural information and may include patterns linked to mental information such as regarding mental states, decisions, intentions, and predispositions. Neural data can also reveal non-mental information such as motor functions, physical health indicators, and reactions to external stimuli. [Neural data can encompass also all information (being it based on personal or non-personal data) that allow inferences about mental states of an identifiable individual.]⁹

The expression **neurotechnologies** includes the spectrum of devices, tools, systems, and algorithms used to understand and/or influence, access, monitor, assess, emulate, simulate or modulate the structure, activity and function of the nervous systems of human beings and other animals. In this definition, these guidelines include "implantable" and "non implantable" neurotechnologies¹⁰.

The expression "**mental privacy**" refers to a specific dimension of the right to respect for private life, as protected under Article 8 of the European Convention on Human Rights and Article 1 of Convention 108+. It encompasses the protection of the individual's mental domain—including thoughts, emotions, intentions, and other cognitive or affective states—against unlawful or non-consensual access, use, manipulation, or disclosure. The right to

⁸ Quote Recommendation on profiling, on health-related data, employment, Guidelines on AI, Guidelines on educational settings.

⁹ Mental information that are closely linked with the definition of neural data are information relating to an individual's mental processes including but not limited to their thoughts, beliefs, preferences, emotions, memories, intentions and cognitive capacities. Such information may be derived from neural activity, as recorded through neurotechnologies, and may provide insights into mental states, mental health conditions, or other individual characteristics related to behaviour, identity, or psychological well-being. Mental information may also be generated through non-neural sources, such as behavioural data, self-reported experiences, psychometric assessments, or data captured by wearable or ambient sensors. Even when not directly linked to brain activity, such information may reveal subjective experiences or internal cognitive states.

¹⁰ The expression "implantable neurotechnologies" refers to technologies that require direct physical integration with the nervous system, such as through surgical implantation of electrodes, probes, or other devices that penetrate biological tissues (e.g., deep brain stimulation implants, neural implants for BCIs).] The expression "non-implantable neurotechnologies" refers to technologies that do not require surgical procedures or direct penetration of biological tissues to collect neural data. These include tools such as electroencephalography (EEG), functional magnetic resonance imaging (fMRI), transcranial magnetic stimulation (TMS), and wearable neuro-monitoring devices. It is worth considering that although they do not involve implantation, non-implantable neurotechnologies may nevertheless be intrusive

mental privacy implies that individuals must retain meaningful control over data that pertain to their inner mental life. This includes both direct representations (such as verbalised thoughts or declared preferences) and inferred mental content derived from neural data or behavioural signals. This right is of particular importance in the context of emerging neurotechnologies and artificial intelligence systems that enable the detection, inference, or alteration of neural activity and mental states. Any interference with mental privacy must comply with the principles of legality, necessity, and proportionality, and must pursue a legitimate aim in a democratic society, in line with established human rights jurisprudence. The protection of mental privacy serves to uphold related fundamental rights, including freedom of thought, freedom of expression, and the right to human dignity and mental integrity.

“Mental integrity” refers to the individual's right to protection against unlawful or unjustified interference with their neural activity, cognitive functions, mental states, or decision-making processes. It safeguards individuals against interventions or processing capable of altering, manipulating, impairing, or exploiting their mental functioning without a valid legal basis and appropriate safeguards, thereby preserving personal autonomy, human dignity, and freedom of thought."

“Statistical purposes” refers to the elaboration of statistical surveys or the production of statistical, aggregated results. Statistics aim at analysing and characterising mass or collective phenomena in a considered population. Statistical purposes can be pursued either by the public or the private sector.

Processing of data for **“scientific research purposes”** aims at providing researchers with information contributing to an understanding of phenomena in varied scientific fields (epidemiology, psychology, economics, sociology, linguistics, political science, criminology, etc.) with a view to establishing permanent principles, laws of behaviour or patterns of causality which transcend all the individuals to whom they apply.

“Historical research purposes” includes genealogical research.

“Archiving purposes in the public interest” can also include archives originating from private entities, where a public interest is involved.

“Consent” means, in line with Article 5 of Convention 108+, when the data processing is carried out on the basis of the free, specific, informed and unambiguous consent of the data subject.

“Medical consent”, in line with Article 5 of the CoE Convention on Human Rights and Biomedicine (ETS No 164) is when an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

I. General Recommendations

1. Establish Clear, Human-centered Objectives

The processing of neural data, and thus the development and use of neuroscience and neurotechnology based on such data should aim at contributing to the improvement of human life, the health, the well-being and dignity of natural persons, the sustainable growth and development and the advancements of democratic societies, in particular for medical, healthcare, research and other significant public interest, and in compliance with applicable privacy and data protection laws and regulations providing appropriate guarantees and safeguards.

It should pursue legitimate aims, be necessary and proportionate to the legitimate purpose recognized by law and be based on publicly available scientific evidence subject to periodic review. It should furthermore be aligned with international laws and standards, notably to secure human dignity, provide for the right to informational self-determination (autonomy), mental privacy, mental integrity, freedom of thought and the principle of non-discrimination and equality.

The lawful and proportionate uses of neural data for healthcare and biomedical research¹¹, including diagnosis, treatment, neurorehabilitation, prevention, and assistive applications as well as clinical investigation constitute a legitimate aim.

Neurotechnological innovation, including in medical, therapeutic, and scientific contexts, should remain proportionate and necessary to the advancement of scientific knowledge and understanding, healthcare, public health, and ensure that privacy and personal data are protected in accordance with Convention 108+ and these Guidelines.

2. Regulate Neural Data Processing, adopt an anticipatory risk assessment

Neural data processing should be carried out on appropriate legitimate bases laid down by law. In accordance with Article 5 of Convention 108+, the processing of neural data should be carried out fairly and transparently (Article 5 (4) (a)), striking a fair balance between all interests concerned, whether public or private, and the rights and freedoms of individuals at stake. Neural data should only be collected for explicit, specified and legitimate purposes and should not be processed in a manner incompatible with those purposes (Article 5 (4) (b)).

To achieve this, all relevant actors involved should conduct prior and ongoing risk-based impact assessments of neural data processing activities which integrate all relevant and appropriate considerations to anticipate risks (anticipatory risk assessment) and to prevent harm. Such assessments should identify, evaluate, and

¹¹ The following instruments collectively cover the definition of diagnosis, treatment, prevention, rehabilitation, assistive technologies and biomedical research involving human participants: Convention on Human Rights and Biomedicine (Oviedo Convention, ETS No. 164); Additional Protocol concerning Biomedical Research (CETS No. 195); WHO International Classification of Health Interventions (ICHI) and WHO definitions of health; where appropriate, ICH Guideline for Good Clinical Practice (ICH E6(R3)) for the concept of clinical investigation.

mitigate risks to human rights and fundamental freedoms of individuals, taking into account evolving technological capabilities, potential societal impacts, and risks of misuse, discrimination, manipulation, or unlawful interference with privacy and mental integrity.

In line with Article 6 of Convention 108+, additional safeguards and guarantees should be established by law. Such safeguards should be comprised of robust technical and organizational measures appropriate to the risks, context, , and the nature, and scope of the processing of the processing. In determining which specific safeguards and guarantees are required under Article 6 of Convention 108+, Parties should take into account not only the intrinsic characteristics of neural data, but also the nature, sensitivity, and potential impact of the inferences that could be derived from such data, whether independently or in combination with other datasets. Particular attention should be paid to inferences relating to health status, mental states, cognitive characteristics, emotions, beliefs, preferences, vulnerabilities, or behavioral predictions, as these may significantly affect the rights and freedoms of data subjects. Paragraph 55 of the Explanatory Report of Convention 108+ lists some possible protections that could be used in legislative actions. These include the data subject's clear consent, a special law that explains the intended purpose and means of the processing or lists the rare situations where processing such data would be allowed, a duty to keep the information secret, steps taken after a risk assessment, and a specific and qualified organizational or technical security measure (like data encryption).

Strengthening legal safeguards and Impact Assessment Requirements

As described above, the processing of neural data may pose unique regulatory challenges, therefore Parties should seek to ensure the highest possible degree of legal certainty, foreseeability, and clarity regarding the legal requirements and conditions applicable to such processing. To this end, the establishment of comprehensive, yet clear and simply understandable rules for neural data processing and ensuring appropriate guarantees and safeguards for individuals' human rights and freedoms, including with regard to the exercise of data subject rights is strongly encouraged.

In specific cases or areas where no specific legislation governing neural data or neurotechnology has been adopted, the data processing should nevertheless remain subject to the requirements of Convention 108+ and to the safeguards and guarantees available under the applicable domestic legal framework consistent with it.

Considering the intrusiveness on the dignity and the right to privacy and of individuals, and the risk of an adverse impact on other human rights and fundamental freedoms, the processing of neural data, thus the use of neurotechnologies based on such data should be subject to specific requirements, including bans to avoid unlawful interference with mental privacy or the manipulation or alteration of mental integrity and ultimately any attempt to harm or negatively affect human dignity and consequently to prevent discriminatory, coercive, manipulative, or exploitative uses of personal data, especially in contexts characterized by power imbalances notably in the fields such as employment and education.

[In other public interest-related fields, such as law enforcement, public security, taxation etc., such data processing may only be permitted if other special categories of data in line with Article 6 of Convention 108+ are allowed. / Special attention should be given to the domestic legislation on the processing of special categories of data in other public interest-related fields, such as law enforcement, public security, taxation etc. and to the extension of the same prohibitions to the processing of neural data in those contexts, fields.]

For non-public interest related purposes such data can only be processed if, and when the necessary guarantees and safeguards have been laid down by law, preventing notably a profound transformation in the reasonable expectation of privacy or the exercise of the right to informational self-determination by individual, therefore the potential disruption in individuals' private life and the society as a whole.

When in the legislative process a human rights and fundamental freedoms related impact assessments is highly recommended that consider a wider view of possible outcomes of the data processing at all stages for all actors involved as per below according to internationally recognized methodology¹².

The provisions of legal frameworks should be guided by the principles of proportionality, necessity, fairness, and respect for human rights, rule of law and democracy; including the right to private life under Article 8 of the European Convention on Human Rights. It should take into account the nature, scope, and potential impact of the processing on individuals' rights and freedoms and should not be determined solely by considerations of technical feasibility, system performance, or economic efficiency. Parties should ensure that appropriate legal safeguards are established for all processing operations involving neural data and that such safeguards are strengthened where the processing is likely to generate heightened risks to the rights and fundamental freedoms of individuals. In addition, Parties should encourage impact assessments that examine the potential effects of neural data processing on privacy and other fundamental rights and freedoms throughout the lifecycle of the processing. .

In accordance with Article 10(2) of Convention 108+, controllers should examine the likely impact of intended data processing on the rights and fundamental freedoms of data subjects prior to the commencement of such processing and throughout its lifecycle where risks evolve over time. Such assessments should adopt a human rights-based and risk-based approach and should consider not only risks to privacy and data protection, but also broader implications for human dignity, mental privacy, cognitive integrity, autonomy, non-discrimination, and democratic participation. Given the specific characteristics of neural data and the sensitivity of mental inferences that may be derived from them, these Guidelines encourage the development and use of specialized impact assessment methodologies adapted to neurotechnology contexts.

In particular, a [Neural Data Protection Impact Assessment (NDPIA)] may be developed or adopted to assess risks arising from the generation of sensitive inferences relating to mental content, emotional states, health status, cognitive traits, or behavioral prediction, particularly where advanced analytics or artificial intelligence

systems are used and may constitute a specialized form of the impact assessment referred to in Article 10(2) of Convention 108+, tailored to the risks associated with the processing of neural data.

An NDPIA should be conducted where processing operations are likely to generate significant risks for individuals' rights and freedoms, including those arising from [An NDPIA should always be carried out as neural data is inherently sensitive, but notably on those instances]:

- the decoding or inference of mental content, emotional states, intentions, or behavioral traits;
- automated profiling or predictive analytics based on neural data;
- large-scale or continuous monitoring of cognitive or affective activity;
- the use of artificial intelligence systems capable of generating sensitive inferences;
- processing involving vulnerable individuals or contexts characterized by asymmetries of power
- cognitive enhancement practices.

Such assessments should evaluate, inter alia:

- the lawfulness, necessity, and proportionality of the processing;
- the nature and sensitivity of the data and inferences involved;
- the likelihood and severity of risks to the rights and freedoms of individuals, in particular vulnerable individuals and minors;
- the adequacy of technical and organizational safeguards;
- the potential for re-identification, discriminatory outcomes, manipulation, coercion, or misuse;
- and the measures implemented to mitigate such risks.

Where residual risks remain significant despite mitigation measures, consultation with the competent supervisory authority should be recommended in accordance with domestic law and the principles of Convention 108+.

In cases involving AI systems, the assessment should specifically examine the risks associated with automated inference generation, profiling, prediction of mental states or behaviors, manipulation, potential discriminatory outcomes, and the possibility that seemingly non-sensitive neural data may generate sensitive inferences about an individual.

The use of impact assessments, including NDPIAs, should not be understood as a purely formal compliance exercise, but as a continuous governance mechanism supporting responsible innovation, accountability, and the effective protection of human rights throughout the lifecycle of neurotechnologies.

Impact assessments such as NDPIAs should not be understood as a mechanism for legitimising processing operations solely because a risk assessment has been carried out. A risk assessment does not automatically resolve data protection concerns and could lead to the conclusion that a certain use of neurotechnologies would not be acceptable.

3. Embed Privacy by Design and by Default approach

Privacy by design and by default is key to ensure that processing of personal data in neuroscience and neurotechnology complies with the principles of Convention 108+. In accordance with Article 10 of Convention 108+, the likely impact of processing on the rights and fundamental freedoms of individuals should be examined before processing begins, and systems, policies, and regulatory frameworks should be designed to prevent or minimize risks from the outset and throughout the lifecycle of neurotechnologies.

This approach is relevant not only to data controllers, but also to legislators, regulators, supervisory authorities, developers, manufacturers, and service providers. It should guide decisions concerning necessity and proportionality, purpose limitation, lawful basis, fairness, transparency, additional safeguards for special categories of data, security, data subject rights, accountability, lawful exceptions, and data transfers¹³. Particular attention is required where neural data processing enables profiling¹⁴, intention prediction, emotion recognition, or the derivation of sensitive attributes.

In such cases, safeguards should be [commensurate/appropriate] with the risks by neural data processing involved and should, include strict purpose limitation, strong access controls, encryption, pseudonymisation where appropriate, human oversight, and measures preventing discriminatory, manipulative, or exploitative uses. These safeguards must also be effective, and their effectiveness must be continuously monitored, developed and adapted.

4. Promote Transparency, Accountability and External Oversight

Given the technical complexity and potential sensitivity of neural data processing, transparency in line with Article 8 of Convention 108+ is essential. Data subjects should receive clear, accessible, and meaningful information regarding the collection, use, sharing, retention, and possible inference generation associated with the processing of their neural data.

Given particular risks posed by neural data processing, transparency obligations under Article 8 should be complemented by appropriate accountability and oversight mechanisms, including regulatory cooperation between data protection and other regulatory authorities, bioethics bodies, and other competent institutions, as well as stakeholder engagement.

An important factor in public acceptance and trust could be the establishment of specialized internal advisory and external oversight bodies with powers to audit, investigate, and advise on or enforce compliance. Such bodies could also serve as empowerment of democratic institutions and processes, such as active engagement, participatory forms of risk assessment, hence contribute to the strengthening of the resilience of democracies in the Parties.

Accountability of data controllers in neural data processing is not a static obligation but a dynamic, continuous and collaborative process. It requires continuous monitoring, adaptation to emerging challenges, and proactive engagement with all

¹⁴ Ref to the Profiling Reco

relevant stakeholders. By embedding robust accountability measures into their practices — including the use of explainable AI — organizations can ensure that neurotechnologies are developed and deployed in a manner that respects and upholds human rights, fosters public trust, and promotes ethical innovation.

5. Guarantee Data Subject Rights and Enforcement Mechanisms

The rights of data subjects under Article 9 of Convention 108+ constitute a cornerstone of the protection framework applicable to neuroscience and neurotechnology. Parties should ensure that individuals are able to effectively exercise their rights in relation to neural data processing, including the rights, not to be subject to a decision without proper consultation, to obtain knowledge of the reasoning of the processing, to object to the processing in the absence of overriding legitimate grounds, to access, rectification, erasure, to have effective remedy where rights under this Convention have been violated, and benefit from the assistance of a supervisory authority within the meaning of Article 15.

It is crucial that individuals who may be impacted by an entirely automated decision can challenge it by presenting their perspective and arguments in a constructive manner when neural data processing is involved. The data subject should be specifically afforded the opportunity to show that the personal data is inaccurate, that the profile is irrelevant, unlawful for their situation, or that there are other factors that could affect the automated decision's outcome before the data is used. This is particularly significant when people are stigmatized because of a specific algorithmic reasoning that is based on neural data processing, especially in public social care and financial sector. (Paragraph 75 of the Explanatory report).

Such a right cannot be exercised if the automated decision is permitted by a law that the controller is bound by and that also specifies appropriate safeguards for the rights, freedoms, and legitimate interests of the data subject. In this situation, though, other rights under Article 9 may be very important, like [the right not to be affected by a decision that is completely automated and has a significant effect on them without their input (littera a.), and] the right to know, upon request, the reasoning behind data processing when the results of that processing are used against them (littera c.). With those rights, or a combination of them, the data subject can find out what factors went into making a decision that affects them and, if they want to, use their right to complain to the supervisory authority.

In the context of health data, rights may also be exercised in a manner that differs from direct access. For example, they may be implemented with the support of a health professional when it is in the data subject's best interest, particularly to facilitate comprehension of the data or to guarantee that the data subject's psychological state is taken into account during the sharing of information.

Given the sensitivity of neural data and the risks associated with its processing in large-scale or interconnected digital environments, Parties and relevant actors should carefully assess whether certain categories of neural data processing should be limited to closed, local, or otherwise protected processing environments, including on-device or compartmentalized systems, in order to reduce risks of misuse, unauthorized access, or secondary exploitation.

Accessible and effective channels should be available for individuals to seek review, lodge complaints before supervisory authorities, and obtain timely enforcement of their rights. Domestic legal frameworks should also provide appropriate judicial and non-judicial remedies, including redress, sanctions and corrective measures, in cases of unlawful neural data processing.

6. Anticipate Risk and Enhance Security

In line with Articles 7 and 10 of Convention 108+, controllers and, where applicable, processors must implement appropriate technical and organizational measures to protect neural data against accidental or unauthorized access, destruction, modification, loss, use or disclosure.

Given the potential impact of neural data processing on private life, mental privacy, mental integrity (autonomy), and non-discrimination of individuals, a proactive and risk-based approach is required. Risk assessments, including where appropriate Neural Data Protection Impact Assessments (NDPIAs), should be anticipatory, continuous, and adaptive, taking into account evolving technological capabilities, emerging threats, and the possibility of sensitive inferences derived from neural data.

The risk for error that can have an impact on the private life of individuals should be set to zero. Where processing presents heightened risks to human rights and fundamental freedoms, controllers must be prepared to suspend, modify, or restrict processing operations and adapt the safeguards or implement additional ones proportionate to the risks identified. This approach aims at anticipating risks in a way that the processing environment can be changed even during the processing (e.g. kill switch, closed environment for processing, hard encryption, human verification, etc.) if indicators foresee a probable risk of unlawful interference with the right to privacy and other human rights.

Robust security measures should include state-of-the-art security measures, including encryption, access controls, secure system architectures, logging and monitoring mechanisms, and clear internal governance structures. Effective breach notification procedures and incident response plans should be established in accordance with applicable legal requirements. Controllers should aim to minimize risks to a level consistent with the sensitivity of neural data and the potential severity of harm. By embedding anticipatory risk management and strong security safeguards, neurotechnological innovation—including in healthcare and research—can proceed within a framework that upholds human rights and public trust.

7. Establish clear rules for the purpose of statistics, scientific and historical research and archiving purposes in public interest

The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is considered as fully legitimate purposes and even as, a priori, compatible for subsequent/further processing provided that other safeguards exist (such as, for instance, anonymisation of data or data pseudonymisation, except if retention of the identifiable form is necessary; rules of professional secrecy; provisions governing restricted access and communication of

data for the above-mentioned purposes, notably in relation to statistics and public archives; and other technical and organisational data-security measures) Such operations, in principle, should exclude any use of the information obtained for decisions or measures concerning a particular individual.

Neural data therefore may be processed for statistics, scientific and historical research and archiving purposes in the public interest where such processing is based on a lawful basis in accordance with Article 5 of Convention 108+, and provided that appropriate safeguards are implemented pursuant to Article 5. Scientific research in the neuroscience field constitutes a legitimate purpose insofar technological developments are used for the only benefit of the scientific research, and the risks to human rights, rule of law and democracy are managed properly to make sure that personal data are processed responsibly within the whole lifecycle of the scientific research and with respect for personal integrity as well as the private life of individual data subjects¹⁵. Scientific research which involves the processing of neural data must therefore be based on an appropriate [lawful/legitimate] basis established in domestic law, which may, depending on domestic legislation, include scientific research as compatible purpose for further processing as defined above, the explicit consent of the data subject in line with Paragraph 56 of the Explanatory Report, or, be based on law, if the processing is carried out in the public interest, by a scientific institution acting under a legal mandate.

It is to be noted however that in the context of scientific research, it is frequently impossible to fully determine the purpose of personal data processing for scientific research purposes at the time of data collection, as stated in Paragraph 43 of the Explanatory Report. As a result, data subjects should be permitted to provide their consent for specific aspects of scientific research that adhere to established ethical standards and data protection laws and regulations. Data subjects should be afforded the opportunity to provide their consent for specific areas of research or components of research projects, provided that the intended purpose is met.

Processing neural data for research or statistical purposes should be assisted by robust safeguards to protect individuals' interests, rights and freedoms and strengthen trust. Such safeguards should include independent external and internal oversight, frequent audits, secure (cf. closed) processing environments, the use of privacy enhancing technologies, protective measures for publication of research results, confidentiality arrangements, conditions for further use. The application of proportionality, data minimization, data quality and purpose limitation principles, the implementation of technical and organizational measures such as pseudonymization or anonymization where feasible, ethical review processes and consultation with supervisory authority where required and relevant are of particular importance. The processing must not be used to make decisions affecting individual data subjects, nor to attempt re-identification, unless this is expressly authorized by law and subject to further safeguards. In all cases, the research purpose must be clearly defined, the rights of data subjects must be respected, and measures must be taken to prevent any risk of misuse, discrimination, or undue interference with privacy.

¹⁵ Cf EDPB guidelines on scientific research

Research and innovation often require the testing and development of new technologies involving the processing of personal data in a controlled environment. To support responsible innovation while ensuring a high level of protection for privacy and personal data, Parties should ensure that the exception regime under Article 11 of Convention 108+ is implemented in a clear and foreseeable manner. In particular, restrictions on transparency obligations or data subject rights for scientific research purposes may only be subject to domestic legislation when – among others – if such measure is provided for by law, respects the essence of fundamental rights and freedoms, and constitutes a necessary and proportionate measure in a democratic society - where there is no recognizable risk of infringement of the rights and fundamental freedoms of data subjects.¹⁶

II. Recommendations for policy makers and supervisory authorities

Policy makers

Policy makers in the public or private sector, including members of parliament, legislators, government officials, and policy advisors play a vital role in setting societal values and legal approaches, as well as implementing standards and legal requirements applicable to privacy and data protection when dealing with new technologies. By following these guidelines, policy makers can ensure that neurotechnologies are developed and implemented responsibly, respecting human rights and promoting trust in the digital environment.

In developing legislation, policies and regulatory measures concerning the processing of personal data in the context of neuroscience and neurotechnology, Parties should ensure that such measures are evidence-based, proportionate and regularly reviewed considering evolving scientific knowledge. Regulatory responses should be grounded in robust scientific evidence regarding both risks and benefits.

Continuous monitoring and periodic reassessment should ensure that human rights are embedded by design and by default in regulation and policy and that regulation remains adaptive, scientifically informed and conducive to responsible innovation, particularly in healthcare and research contexts.

1. Carry out regulatory and legislative/policy impact assessments

Before adopting or amending legislation or policies concerning neuroscience and neurotechnology, Parties should conduct a prior regulatory or legislative impact assessment. Such assessments should evaluate compatibility with the right to privacy and other human rights, in line with the principles set out in Convention 108+ and the General Recommendations above. Moreover, due to the special implications deriving from neurotechnologies it is important that within the legislative process, a wider view of the possible outcomes of data processing extended not only to human rights and fundamental freedoms but also to the functioning of democracies and social and ethical values is applied.

¹⁶ For the implementation of these latter criteria the [Guidelines on the general principles of Article 11 of the Modernised Convention 108](#) could be of use.

. The findings of the impact assessment process should receive appropriate consideration, for example through the elaboration of a report to be submitted for review to competent independent bodies, including supervisory authorities under Article 15 of Convention 108+ and be presented as integral part of a draft law or bill. The content of the impact assessment should cover all elements listed in [I.4] and give clear indications concerning the quality of the law/policy (i.e. that it should be accessible and foreseeable as per the ECtHR case law and contain sufficient detail).

2. Organise regulatory forums, stakeholder consultation

To foster the appropriate dialogue with different segments of society and interests at stake, policy makers should invest in regulatory forums and consultation of stakeholders including civil society and in particular data subject representative associations.

Such forums would be particularly beneficial for discussing the impact assessment procedures, as described in II.1, and their outcomes. The opinion of internal, external ethic committees, notably the ones on bioethics, oversight bodies or institutions, specialised scientific researchers should also be shared and discussed.

Such participatory processes enhance legal quality, public trust and democratic resilience, while ensuring that innovation in healthcare and research remains aligned with human rights standards.

3. Consider legislation/policy making early

Whether to regulate or not is a sovereign decision of countries, but from a privacy and data protection point of view, an early domestic legislation covering personal data processing carried by/in neuroscience and neurotechnology may have multiple benefits, notably:

- a) legitimate purposes for the processing of personal data in this area could be set in law while postulating red lines where the application of neurotechnologies would not be permissible as per the General Recommendations
- b) the legitimate basis (or if applicable several bases) for the processing could also be provided by the national legislation, without prejudice to the need to ensure the appropriate guarantees and safeguards as described in these Guidelines are put in place as early as possible. Clarity and legal certainty could be ensured for the processing of personal data and on the additional appropriate safeguards with regard to the processing of special categories of data in line with Article 6 of Convention 108+
- c) [Furthermore, in light of the highly sensitive information that their processing may potentially reveal, and with reference to the relevant provisions of Convention 108+ and by analogy with existing legal precedents, domestic legislation may provide that the enhanced

protection applicable to special categories of data under Article 6 of Convention 108+ is extended to [all] neural data.]

- d) specific (high-level) security measures according to Article 7 of Convention 108+ could also be fixed in the law; the exception regime(s) in line with Article 11 of Convention 108+ could also be clearly and transparently regulated to ensure that the exceptions in the domestic law are in line with a pressing social need and fulfil all criteria laid down in the Convention, its Explanatory report and the [Guidelines on the general principles of Article 11 of the Modernised Convention 108](#).

Legislation should ensure that health-related neural data processing for legitimate medical and scientific purposes is carried out while maintaining reinforced appropriate safeguards for the rights and freedoms of data subjects in line with applicable data protection regulations that are commensurate/proportionate with the sensitivity of such processing.

4. Ensure Effective Exercise of data subject rights and enforcement

To ensure an effective and timely exercise of data subject rights, including the right to administrative and non-administrative remedies, according to the General Recommendations provided above, policy makers and regulatory authorities should cooperate with all relevant stakeholders, notably national and supra-national courts in designing an ecosystem which ultimately upholds this objective[/ As per the general recommendation policy makers should provide an ecosystem which upholds the objective of ensuring data subject rights by providing complementary and efficient remedies/]

5. Consider specific data transfer arrangements

All transborder data flow must comply with Art. 14 of Convention 108+ and be accompanied by appropriate safeguards to prevent misuse, unauthorized access, and privacy risks. When laws outside of the Parties of Convention 108+ might not ensure an appropriate level of protection yet, policy makers and regulators should consider even more the necessity of specific neural data transfer arrangements. Such arrangements could be built on existing pre-approved standardized contractual clauses¹⁷, on specific neuroscience, neurotechnology ad-hoc contractual clauses (yet to be developed), or other tools of similar nature and effect (such as BCRs, technical standards, code of conduct, certification, etc.). These safeguards should include, but are not limited to, encryption, access controls, and strict data handling protocols to ensure data security in transit and at rest.

Finally, regardless of the legal basis for transfer, all transborder data exchanges must ensure that human rights, including privacy and human dignity, are not undermined. As for the processing of neural data, transborder data flows should be subject to the same legal requirements and conditions to ensure that such data enjoys the same level of protection than in the country of origin. For this, ad-hoc contractual clauses or

specialised extension to BCRs, standard contractual clauses that incorporate all the requirements and conditions as specified above should be made available and duly agreed upon before any transfer of such data. At the same time, Parties are encouraged to facilitate secure and responsible trans-border data sharing for scientific research, healthcare, and public health purposes, including through harmonised standards, and international cooperation mechanisms consistent with Convention 108+.

If the neural data processing in certain sector (employment, education) or for certain purposes (high-risk processing, neuromarketing, deceptive or manipulative practices and unauthorised commercial uses) is not authorised domestically, international transfers should also be restricted or suspended.

To elaborate guidance, approve and make available necessary tools and participate, if applicable and appropriate in transborder enforcement cooperation actions carried out by the group of supervisory authorities created based on Article 17 of Convention 108+ could be of particular relevance.

6. Prohibit high-risk processing, neuromarketing, deceptive or manipulative practices and unauthorised commercial uses

Neurotechnologies capable of inferring, influencing, or manipulating mental states may pose very significant risks to data subjects' mental privacy, personal autonomy, and cognitive integrity. Particular attention should be paid to commercial practices, including forms of neuromarketing or behavioral profiling that exploit cognitive vulnerabilities, emotional states, or developmental characteristics, especially in relation to children and other vulnerable individuals.

Processing of neural data, including for commercial purposes, that rely on covert/non-consensual monitoring of data subjects', their online behavior, their profiling, in particular for manipulative or deceptive purposes, or for emotional influencing or exploitation, or the generation of sensitive inferences [must] be prohibited. Particular caution is required in situations characterized by power asymmetries, dependency, or impaired decision-making capacity, where consent cannot be genuinely free.

[Data subjects, even outside of the scope of these activities must retain the right to object to the processing of their personal data for commercial profiling, targeted advertising, neuromarketing, or other manipulative practices.]

7. [Prohibit the processing of neural data of] minors and protect Individuals belonging to Vulnerable Groups

[The processing of neural data of minors should not be authorized/outside of the medical field/ due to the extreme sensitivity of such data, the impact such processing could potentially have on their private life and their development.]

In addition, supervisory authorities should be invited to raise the awareness on the impact of neurotechnologies and the processing of personal data related [to minors and] individuals belonging to vulnerable groups in line with Article 15 para 2 lit. e taking

always into account [the best interest of the child] and the principle of non-discrimination. In particular, the following recommendations should be considered: a) raising the awareness and involve parents, legal guardians or representative organizations in the policy making, b) providing specific and specialized safeguards that take into account the degree of vulnerability of such groups. c) Requiring ethical reviews and age-appropriate legal basis/bases (such as consent/assent procedures) for research or other legitimate purposes of the processing of data related to minors. d) Introducing special safeguards for vulnerable adults, ensuring that the legitimate basis or bases for the processing of such data is and remain valid throughout the whole process with the appropriate support for decision-making on revoking, confirming consent, if applicable and where needed.

Supervisory authorities

Supervisory authorities established by Article 15 of Convention 108+ play an essential role in both participatory policy making and enforcement of rights and domestic data protection legislation. Supervisory authorities must be independent and impartial and empowered to be able to appropriately fulfill their functions in the context of neuroscience and neurotechnology also having in mind the increasing transborder enforcement cooperation based on Article 17 of Convention 108, which plays a particularly important role in the field of neurotechnologies.

1. Allocate Adequate Resources:

Supervisory authorities should be well-funded, staffed, and trained to oversee neural data processing activities effectively, also with a view to building specialized teams with expertise in neurotechnologies and mental privacy to address the unique challenges posed by the processing neural data.

2. Promote Cross-Border Cooperation:

Supervisory authorities based on Article 17 of Convention 108+ should promote collaboration with other supervisory authorities operating in a different jurisdiction to ensure consistent enforcement of neural data protection laws, particularly in scientific research and related transborder data flows contexts.

3. Consultative Role in Law and Policy

Under Article 15(3) of Convention 108+, supervisory authorities must be consulted on legislative or administrative measures and policies relating to personal data. Supervisory authorities should be engaged from the earliest stages of neurotechnology-related policymaking, in particular in the legislative impact assessment as recommended above, to ensure human rights are embedded by design and by default.

4. Soft law and Regulatory Guidance

Supervisory authorities are invited to issue expert opinions on neural data processing operations that pose high risks, particularly regarding mental privacy, automated profiling, and biometrics, in particular in order to inform national policies and legislation or sectoral codes of practice.

5. Awareness Raising and Public Engagement

Policy makers should invest resources in digital literacy and education to increase data subjects' awareness and understanding of neural data processing and its related applications and their effects. They should also encourage professional training for neural data developers to raise awareness and understanding of the potential effects of this new technology on individuals and society. They should support scientific research in human rights-oriented neuroscience. In accordance with Article 15.2.e, supervisory authorities should proactively inform the public of their role, responsibilities, and activities in the neurotechnology domain, and promote public awareness of the rights of data subject rights and the awareness of controllers and processors of their responsibilities under the Convention. This includes publishing reports, guidance documents, and engaging in media outreach to promote understanding and trust.

6. Stakeholder Collaboration and inclusive dialogue

Supervisory authorities could consider cooperating with researchers, developers, civil society, to ensure evolving practices in neurotechnology remain widely accepted and aligned with the principles of human rights.

Structured mechanisms to allow the engagement of supervisory authorities with relevant stakeholders, particularly vulnerable populations and underrepresented groups, should be established to ensure responsive and inclusive regulation and policy.

7. Participation in Human Rights Impact Assessments

Supervisory authorities are encouraged to provide guidance and cooperation to facilitate the impact assessment controllers are required to carry out according to Article 10 (2) of Convention 108+. Supervisory authorities are also encouraged more specifically related to neuroscience and neurotechnology to support or co-lead Human Rights Impact Assessments (HRIAs), including expanded Neural Data Protection Impact Assessments (NDPIAs), to ensure comprehensive risk evaluation and mitigation in neurotechnology design and deployment. They are also encouraged to actively engage in discussing and developing an internationally recognized methodology, such as HUDERIA¹⁸.

8. Regulatory Forums and Best Practices

Participation in national and international forums—alongside other regulators and expert bodies—should be prioritized to inform policy making and to coordinate

¹⁸ HUDERIA: The **risk and impact assessment of AI systems from the point of view of human rights, democracy and the rule of law (HUDERIA)** provides structured guidance for assessing the risks and impacts of AI systems with regard to the protection and promotion of human rights, democracy and the rule of law. More on the methodology: [HUDERIA - risk and impact assessment of AI systems - Artificial Intelligence](#)

enforcement strategies, to participate in enforcement cooperation (when applicable) and share evolving best practices.

III. Recommendations for developers, manufacturers and service providers

Developers, manufacturers and service providers hold critical responsibilities in ensuring that neurotechnologies are designed, developed, and deployed in ways that are consistent with human rights and comply with privacy and data protection laws, including Convention 108+. The following recommendations support responsible innovation and legal compliance throughout the lifecycle of neuroscience and neurotechnological systems:

1. Human Rights-Centered Design

In line with the general recommendation (Chapter I) it is recommended to initiate at a very early-stage processes which embed privacy and personal data protection and overall, all human rights considerations by design and by default. Such goals can be achieved when integrating the protection of privacy, personal autonomy, mental integrity and other human rights related into the design, development, and deployment of neurotechnologies.

It is of primary importance for controllers to carry out the Privacy Impact assessment (PIA) as foreseen by Article 10 of Convention 108+. PIA should be tailored to the peculiarities of neuroscience and neurotech to specifically assess and mitigate risks to the rights and fundamental freedoms of data subjects, including privacy, human dignity, mental integrity and personal autonomy at every stage of product development. Such assessment could be followed by Human Rights Impact Assessments (HRIAs), including expanded Neural Data Protection Impact Assessments (MDPIAs) to thoroughly factor and mitigate the risks to other human rights. It is highly recommended that such assessment considers a wider impact of the use of the new technology to considerations related to the rule of law and democracy according to internationally recognized methodology (such as HUDERIA).

Where system architectures enable the decoding, prediction or inference of sensitive mental content or behavioral patterns, developers should implement heightened technical and organizational safeguards, including separate mainframe, strict access policy on need-to-know basis, access restrictions, logging system for operations and security logs and independent oversight mechanisms.

Particular caution should be exercised where neural data are used to develop digital replicas, synthetic personalities, "deadbots", or similar systems intended to simulate the identity, memories, behavioral characteristics, or mental traits of an individual. Such processing may create heightened risks for privacy, dignity, identity, and the rights of data subjects and third parties and raise ethical issues. It should therefore be subject, if at all allowed by domestic legislation in specific cases, to enhanced safeguards and guarantees, including strict access policy, specific transparency notice, security measures, logging of operations and security appropriate oversight, while ensuring the right of the data subjects not to be subject to decisions significantly affecting them based solely on an automated processing of data without having their

views taken into consideration and the right to request the reasoning of a decision that has an effect on them.

[In cases where the creation of “deadbots” based on neural data, is not [in line with domestic legislation and] accompanied by prior evidence of the express consent of the deceased person, as well as the commercialization of their neural data after their death, should however be explicitly prohibited.]

If the data processing is combined with AI applications or their agent(s) it needs to be ensured among others that AI systems used in neurotechnologies are explainable, allowing individuals, auditors, and regulators to understand how decisions are made and ensuring accountability for any outcomes¹⁹.

In healthcare and scientific research contexts, where there is no recognisable risk of infringement of the rights and fundamental freedoms of data subjects, impact assessment and compliance procedures should remain commensurate/proportionate to the risks at stake for interests, rights and fundamental freedoms of the data subjects. Such adaptation should be done in line with Article 10 of Convention 108+, considering the nature and volume of data processed, the nature, scope and purposes of the data processing and, in certain cases, the size of the data controller.

Streamlined review procedures which may be provided for low-risk or non-invasive research activities should in all cases maintain appropriate guarantees and safeguards for privacy, security, and other human rights and fundamental freedoms.

Developers, manufacturers and service providers should put in place mechanisms which allow data subjects to easily exercise their rights.

2. Fair, Transparent and Sustainable Data Practices

Transparency is an obligation under privacy and data protection laws, notably in Article 8 of Convention 108+. Establishing robust transparency framework and mechanisms contributes greatly to informing appropriately users about how their neural data will be collected, processed, shared, and stored and by whom exactly, allowing informed and aware choices.

[In line with legitimacy considerations, a fair balance needs to be stricken at all stages of the processing between all interests concerned, whether public or private, and the rights and freedoms at stake.]

Ensuring the right choice on a legal basis or bases could also have a positive impact on the right design choices just as well as all early considerations related to the adherence with the principles of necessity and proportionality and purpose limitation. Effectiveness and efficiency of the system can greatly improve if principles related to data quality (article 5) and data minimization principle with clear deletion protocols are embedded in the design of such system implying that processing only good quality of neural data that is preserved in a form which permits identification of data subjects for

¹⁹ Poss: reference to AI Framework Convention for other conditions that need to be looked at and ensured

no longer than is necessary for the purposes for which those data are processed. In healthcare and scientific research contexts, developers and providers should design systems that maximise therapeutic and rehabilitative benefits while strictly adhering to necessity, proportionality and data minimisation requirements.

Clear governance frameworks should be established for secondary use for scientific research or statistical purposes, including the principle of compatible purpose, transparency regarding such purposes, applicable safeguards, and where appropriate, independent external oversight.

3. Security of Neural Data

[In line with Article 7 of Convention 108+, data security considerations in today's digital world are key. It is paramount to adopt state-of-the-art security measures to prevent unauthorized access, use, disclosure, misuse, alteration or loss of personal data. This includes among others implementing advanced cybersecurity protocols providing for strong encryption, secure storage, user credential distribution, logging traceability and regular security audits.

The appropriate level of data security must be maintained during transborder data flows.

Developers and providers are encouraged to support secure data-sharing infrastructures and interoperable technical standards ensuring convergence enabling responsible scientific collaboration, including in cross-border research contexts, while ensuring compliance with Convention 108+ and applicable safeguards for transborder data flows.

Consideration could be given to whether certain security risks that may be particularly relevant in the context of neural data processing, such as side-channel attacks or other risks associated with neurotechnological devices and interfaces, should be expressly addressed and effectively mitigated by developers, manufacturers and service providers.

4. Oversight and Internal Accountability

Developers, manufacturers and service providers of neuroscience and neurotechnology are strongly recommended to establish internal governance frameworks to facilitate compliance with data protection and other human rights principles. In particular the following measures could be considered: a) to create dedicated governance teams or ethics committees. b) to put in place a data protection function to oversee compliance with data protection laws in neural data processing. c) to engage independent third-party auditors to assess compliance with ethical standards, legal obligations, and technical safeguards. d) to develop accessible complaints procedures for individuals to lodge complaints regarding data processing and seek redress for violations of their rights.

5. Special Protections for Vulnerable Populations

In line with policy making related considerations (in chapter II) developers, manufacturers and service providers of neuroscience and neurotechnology must not engage in harmful applications, such as neuromarketing, behavioral manipulation, or covert profiling. Strong safeguards tailored [for minors], persons with cognitive impairments, and other vulnerable groups, such as simplified information, adequate support for providing valid consent, and strict profiling restrictions should be implemented.

6. Collaboration and Standard Setting

Consideration of the perspectives, needs and interests of different segments of society is of prime importance. Developers, manufacturers and service providers should engage with stakeholders, involving civil society, researchers, affected communities, and policymakers before and throughout development and deployment phases in order to duly consider the different interests at stake and orient their decisions accordingly.

In addition, developers, manufacturers and service providers should support ethical and technical standardization: promote convergence and alignment to and with the norms expressed in international standards such as in Convention 108+ in privacy and data protection and other relevant international frameworks governing neural data and AI ethics is crucial to adequately protect ethical and human rights standards while ensuring legal certainty²⁰.

7. Regulatory Cooperation and Reporting

To ensure maximum transparency and sustainable data governance (III.2) regular engagement in audit or cooperation activities with supervisory authorities are highly recommended. Such active engagements should cover notably the mapping of processing operations, measuring appropriateness of safeguards, and updating Privacy, Human Rights and Neural data Protection Impact Assessments.

If operations expand on several jurisdictions cooperation with regulators in the concerned jurisdiction is highly recommended just as well as the integration of internationally recognized best practices into system as improvements.

Developers and providers are also encouraged to contribute to public awareness and transparency initiatives concerning the societal benefits, limitations, and risks of neuroscience research and neurotechnologies.

²⁰ References (UN, OECD, UNESCO, CoE AI Framework Convention, Oviedo convention?)