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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**

INDEX

to be drafted as a final step

Introduction

The rapid advancement of neurotechnologies has introduced unprecedented opportunities for understanding, monitoring, and modulating human brain activity. Neurotechnologies encompass a broad spectrum of tools and systems, from brain-computer interfaces and neural implants to neuroimaging and neuromodulation techniques. These technologies hold transformative potential for neuroscience, clinical care, rehabilitation and improvement of quality of life. However, they also raise [profound/complex] ethical, legal, and societal challenges, particularly regarding the collection, and processing of neural data, and the protection of the most intimate part of privacy of the individuals whose data are processed.

Neural data — information derived from the human nervous system, including brain activity patterns and neural signals [— may, depending on the context, constitute personal data and, in many cases, sensitive data due to its potential to reveal highly intimate aspects of an individual's cognitive states, mental health, behavior, or identity, thereby posing unique regulatory challenges. The processing of such data offers great promise for advancing neuroscience and medicine, including in the understanding of the human brain as well as in the diagnosis and treatment of neurological and psychiatric disorders. At the same time, it poses particularly significant risks, including unlawful interference with individuals' privacy, breaches of data protection laws, unauthorized surveillance, or manipulative uses and practices. Against this background, it is crucial to ensure the strict application and effective enforcement of existing legal frameworks, notably Convention 108+, and, where appropriate, the adoption of specific safeguards tailored to the particular sensitivity and potential impact of neural data processing. [In line with the human rights-based approach of the Council of Europe, any development, research, or application of neurotechnologies should pursue legitimate aims, be necessary and proportionate in a democratic society, and incorporate appropriate safeguards and technical and organizational measures to ensure the protection of personal data, including through data protection by design and by default. Special attention should be paid to preventing discriminatory, coercive, or exploitative uses, especially in contexts characterized by power imbalances or vulnerability]., neural data concerns the most intimate part of the human being and is inherently sensitive as it may reveal deeply intimate insights into an individual's identity, thoughts, emotions and preferences. The processing of such data is susceptible to lead to serious discriminatory practices in the absence of appropriate safeguards and guarantees. These risks necessitate a reaffirmation and enforcement of existing human rights and data protections frameworks to address the unprecedented challenges posed by neural data in the digital age.

Being aware of the profound implications on individuals and society which may derive from the processing of neural data, special attention shall be given to protecting human dignity and personal autonomy¹.

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 its modernized version, (Protocol CETS No 223 amending Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data, “Convention 108+”), safeguard the right to privacy and to the protection of personal data. [In accordance with the principles enshrined in (Convention 108 and “Convention 108+”, the processing of neural data must respect human dignity and human rights, in particular the right to private life and the right to the protection of personal data. The processing of personal data for the development and deployment of neurotechnologies should therefore be guided by the principles of necessity and proportionality, lawfulness, fairness, transparency, purpose limitation, data minimization, accuracy, storage limitation, integrity, confidentiality, and accountability. It is important to highlight that both ethical and security considerations remain critical to prevent misuse and uphold public trust in neurotechnologies and also that many protections mentioned in these guidelines are not only ethical imperatives but legal obligations under data protection and human rights frameworks./These instruments enshrine binding principles applicable to all personal data processing, including necessity and proportionality, purpose limitation, lawfulness, fairness, transparency, data minimization, data quality, storage limitation, security, accountability, and the requirement that processing be necessary and proportionate to legitimate aim pursued the universal and individual right to privacy and offer transposable standards for the protection of personal data, notably by providing that personal data should be processed lawfully, for legitimate purposes and in a proportionate way related to those predefined purposes. Convention 108+ provides principles for strengthened security including in the digital environment or in cyberspace by prohibiting unauthorized use, access, disclosure, and misuse] These principles need to be interpreted regarding complex and evolving technological contexts, such as neuroscience and neurotechnology. In addition, the characteristics of neural data require additional normative efforts to interpret and adapt these principles to neurotechnologies as no such data were specifically discussed in any of the existing Council of Europe instruments.

These Guidelines therefore propose to apply the principles enshrined in Convention 108 and Convention 108+ to neural data and the processing of personal data in and by neurotechnology to ensure that privacy and data protection rights remain appropriately safeguarded and guaranteed in line with international standards.

Neurotechnologies and the processing of neural data fall within the scope of these principles whenever such data relate to an identified or identifiable individual. Given the potential of neural data to reveal highly sensitive information about mental states,

¹ 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 ».

health conditions, cognitive patterns, or behavioral traits, such processing may in many cases qualify as the processing of special categories of data within the meaning of Article 6 of Convention 108+. This requires the application of appropriate safeguards, enshrined in law, complementing those of the Convention, including enhanced security measures.

These Guidelines reflect the realities of the digital age and address novel challenges associated with neural data processing, including the lack of ready-made legal framework at international but also at national level, the risk of re-identification even from anonymized neural data, the need for that the processing of personal data is carried out on a valid legal basis, for legitimate purposes, and the importance of implementing the purpose limitation principle in this context. Regulatory attention should not focus exclusively 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 behavioural, biometric, social media or contextual data), particularly where advanced analytics or artificial intelligence systems are used.

Certain categories of inferences may pose heightened risks to mental privacy, autonomy and non-discrimination, 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.

[Where processing operations are [capable of] generating such sensitive inferences, additional safeguards consistent with Articles 6 [and 10] of Convention 108+ should be put in place as described by these Guidelines.]

Convention 108+ provides guarantees and safeguards for the processing of personal data including in important public interests, notably public health and scientific progress, by requirements of legality, necessity, and proportionality and application of data protection by design and by default.

At the same time, the specific characteristics of neural data—including the possibility of inferring subconscious or highly intimate information, the risk of re-identification from seemingly anonymised datasets, and the emergence of behavioural profiling—poses additional challenges to ensure that data subjects remain in control of their data and continue enjoying an enabling environment for informational self-determination.

These Guidelines provide an interpretation of the provisions of Convention 108+ tailored to neural data processing. They clarify requirements on the valid legal basis for the processing of personal data, on the principle of necessity and proportionality and purpose limitation as well as on a so called anticipatory risk assessment in light of evolving technological capabilities and proposes solutions on how to put in place all guarantees, safeguards, lawful exceptions, etc. based on the provisions of the Convention. e. i.

Furthermore, these Guidelines give practical recommendations for situations in which neural data intersect with other special categories of personal data, including but not restricting to **biometric data** when uniquely identifying a person and health-related data. In such cases, the adoption of safeguards 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.

[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. 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.]

The Guidelines [contain three chapters of main, high level, yet practical recommendations and an explanatory note and a glossary of definitions in its annex]. By addressing to three main actors (i.e. legislators, regulatory authorities and developers, manufacturers and service providers) that are facing or might face 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 cognitive integrity and promotes responsible innovation in neuroscience.

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.

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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 behavioral information and may include patterns linked to mental information such as regarding mental states, decisions, intentions, and predispositions. Neural data can also be used to reveal non-mental information such as motor functions, physical health indicators, and reactions to external stimuli.

The expression "**implantable neurotechnologies**" refers to technologies that require direct physical interaction 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.

The expression "**mental information**" refers to 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 and shall therefore be treated with heightened protection where it is capable of identifying or inferring sensitive attributes of the data subject.

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 5 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 mental privacy implies that individuals must retain meaningful control over data and information 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.

I. General Recommendations

1. Establish Clear, Human-centered Objectives

The development and use of neuroscience and neurotechnology should follow legitimate, aims, necessary and proportionate objectives recognized by the law that are based on publicly available scientific evidence subject to periodic review and aligned with international norms and public interest. [Objectives and regulatory measures should be grounded in verifiable scientific evidence and subject to periodic review.]

The lawful and proportionate uses of neural data in healthcare, including diagnosis, treatment, neurorehabilitation, prevention, and assistive applications are to be recognized as such legitimate aim.

Individuals should always be at the center of public or private strategies that need to secure human dignity, informational self-determination (autonomy), mental privacy, cognitive integrity and the principle of non-discrimination.

Neurotechnological innovation, including in medical, therapeutic, and scientific contexts, should be fostered where necessary and proportionate to demonstrably serve the well-being of individuals and society, while ensuring that privacy is protected and personal data are processed in accordance with Convention 108+, as described in these Guidelines.

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

[Neural data processing /Neuroscience and neurotechnology] should be regulated by law. The law should clearly specify that the processing of neural data is carried out fairly and in a transparent manner, striking a fair balance between all interests concerned, whether public or private, and the rights and freedoms at stake. It is important that the law clarifies that such data can only be collected for explicit, specified and legitimate purposes and not processed in a way incompatible with those purposes.

To achieve this, all actors involved should conduct an anticipatory risk assessment which aims [to cause zero/prevent] harm to individuals, society and inclusive economic growth. This could be achieved notably by applying the principle of fairness² and transparency at all stages of data processing and by carrying out and systematically updating risk assessments at various levels as described below.

Given the potential sensitivity of neural data, it should be ensured that data falling under Article 6 of Convention 108+, are assisted by robust safeguards established by law and measures both at operational and technical level as per below to ensure additional protection in line with Article 6 of Convention 108+. In determining whether enhanced safeguards are required under Article 6 of Convention 108+, Parties should take into account not only the intrinsic characteristics of neural data, but also the sensitivity of inferences reasonably likely to be drawn from such data.

3. Strengthening legal basis and Impact Assessment Requirements

The processing of personal data in neuroscience or by neurotechnology should be carried out on a valid legal basis. It is of high importance to have the utmost clarity in the domestic legal framework about the lawful basis of processing in different contexts. Therefore, it seems that a law and/or a legal framework would be desirable to be established in all jurisdictions to ensure this clarity and foreseeability and to clearly provide with the appropriate guarantees and safeguards for those legal bases. It is recommendable to differentiate in the underlying legislation or otherwise between the

criteria for valid legal basis when the processing is performed on special categories of data and “non-special” categories of data, in line with Convention 108+³.

Encourage human rights and fundamental freedoms related impact assessments 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 methodology⁴. When appropriate and available specific methodologies with particular attention to cognitive and mental risks (e.g. via a Mental Data Protection Impact Assessment – MDPIA) should be developed/adopted. Furthermore, they should assess the likelihood that the processing may generate sensitive inferences relating to mental content, emotional states, health status, or behavioral prediction, particularly where AI systems are involved.

4. Embed Privacy by Design approach

Privacy by design is key to ensure that processing of personal data is based on the principles of Convention 108+. It is a very practical approach to take all elements into consideration already at the design phase, but also through the life-cycle of neurotechnologies being it for the legislator, regulator or data controllers: notably necessity, proportionality, purpose limitation, legitimate basis for the processing, fairness, transparency, heightened protection for special categories of data, data security, data subject rights, accountability, lawful use of exceptions⁵ and clear and easily adaptable use for data transfers⁶.

Particular care is required where profiling based on special categories of data⁷ (i.e. neural data may enable profiling, behavioural inference, or the derivation of sensitive attributes.) and what could be the acceptable safeguards commensurate to the risks involved in such areas and what could be the benchmarks to measure “if the data are (strictly) necessary for the lawful and specific purposes of the processing”.

5. 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. High emphasis should be given to find ways of efficiently providing appropriate information to the public on the data processing undertaken by the data controller.

Such processes could be informed by a) regulatory forums for cooperation between data protection authorities, bioethics bodies, and other relevant institutions and b)

³ Reference to the ER (explicit/written consent, etc.)

⁴ such as the privacy impact assessments based on Article 10 of Convention 108+ and the HUDERIA methodology to be developed by The Steering Committee for New and Emerging Digital Technologies (CDNET))

⁵ Ref to the guidelines on Article 11

⁶ Reference to MCC

⁷ Ref to the Profiling Reco

stakeholder engagement processes at all stages of policy development to ensure transparency and trust.

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

6. Guarantee Data Subject Rights and Enforcement Mechanisms

Data subject rights (Article 9) are one of the cornerstone of Convention 108+ and are a result of almost half a century of standard setting activities, case-law by the ECtHR and high considerations given to a changing depth and scale of automated data processing, including by new technologies, notably in areas where very little or no automated processing existed widely. Therefore, it is recommendable, also in conjunction with the previous point on maintaining trust, confidence and public acceptance to create an environment for neuroscience and neurotechnology where data subject rights being it traditional ones or the “new generation” ones can be guaranteed to all individuals within the jurisdiction of countries, in the operation of private actors.

Thorough considerations seem to be necessary to decide whether the processing of neural data would not only be allowed in a closed digital environment (on device, dedicated digital environments for such processing) keeping it away from general use on the internet.

Channels for individuals to turn to regulatory authorities should be established with preferably effective and timely outcome on the enforcement, if necessary, of their rights.

Ensure that judicial and non-judicial sanctions and remedies are also foreseen in the domestic legal framework of countries.

7. 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, alteration, loss, misuse or disclosure.

[Given the potential impact of neural data processing on private life, mental privacy and autonomy, a proactive and risk-based approach is required. Risk assessment should be anticipatory, continuous and adaptive, taking into account evolving technological capabilities and emerging threats. Where indicators reveal a heightened risk of unlawful interference with human rights, notably with the right to privacy controllers should be prepared to suspend, modify or restrict processing operations. / The risk for error that can have an impact on the private life of individuals should be set to zero. It requires as proposed above an anticipatory approach which not only contains an internationally recognized proactive risk mitigation strategies but aims at anticipating risks in a way that the processing environment can be changed even during the processing (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 minimise 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.

II. Recommendations for policy makers and supervisory authorities

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 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 digital identity systems.

In developing legislation, policies and regulatory measures concerning neuroscience and neurotechnology, Parties should ensure that such measures are evidence-based, proportionate and regularly reviewed in light of 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 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.

As this is already practice in some international organizations⁸ and best practices in this area has already been made available⁹ it should only be emphasized that such assessment needs to consider the impact on the right to privacy and more broadly on other human rights. The findings of the impact assessment process could be summarised in an impact assessment report which could then be sent for review by an independent body having the possibility to issue opinions. 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 and contain sufficient detail).

2. Organise regulatory forums, stakeholder consultation

In addition to internal coordination procedures (which could also expand on the privacy and data protection chapter of the assessment report) it is advisable to organise regulatory forums and stakeholder consultations. Given the possible impact of the neuroscience and neurotechnology, it could be of high relevance to organise such forums where the outcome of the impact assessment procedures as described in II.1 could be discussed. It seems to be desirable that the opinion of internal, external ethic committees, notably the ones on bioethics, oversight bodies or institutions, specialised scientific researchers are also 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 seems to have multiple benefits, notably:

- a) In relation of the two previous points legitimate objectives/purposes for the processing of personal data in this area could be set in law.
- b) The lawful basis (or if applicable several bases) for the processing could also be provided by the national legislation with all the necessary guarantees and safeguards as described in these Guidelines.
- c) Clarity and legal security could be ensured for the processing of special categories of data and on the appropriate safeguards that need to be put in

⁸ Reference to EU [Impact assessments - European Commission](#)

⁹ Reference to OECD Regulatory impact assessment:
[google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwiThNSWyNOSAxUx4QIHXXIQGL8QFnoECD0QAQ&url=https%3A%2F%2Fwww.oecd.org%2Fcontent%2Fdam%2Foecd%2Fen%2Fpublications%2Freports%2F2020%2F02%2Fregulatory-impact-assessment_0bf78a03%2F7a9638cb-en.pdf&usq=AOvVaw3esj3Go3MVwDlkDP7vq30c&opi=89978449](https://www.oecd.org/content/foeod/fpublications/freports/f2020/f02/fregulatory-impact-assessment_0bf78a03/f7a9638cb-en.pdf&usq=AOvVaw3esj3Go3MVwDlkDP7vq30c&opi=89978449)

place complementing the ones already existing for “non-special categories” of data in line with Article 6 of Convention 108+,
d) specific (high-level) security regimes could also be fixed in the law, e) the exception regime(s) in line with Article 11 of Convention 108+ could also be clearly and transparently regulated.

Legislation should ensure that health-related neural data processing for legitimate medical and scientific purposes is facilitated/carried out while maintaining reinforced safeguards appropriate to the sensitivity of such processing.

4. Ensure Effective Exercise of data subject rights and enforcement

Article 9 considers data subject rights that have to be ensured for data subjects in the Parties of Convention 108+.

To ensure an effective and timely exercise of those rights policy makers and regulatory authorities should cooperate in designing an ecosystem which ultimately uphold this objective. To facilitate that the closed processing of neural data as recommended above could also be considered.

The overall integration (in line with Article 12 of Convention 108+) of those rights when exercised in relation to data processing operations carried out by neuroscience or neurotechnology in the national administrative, civil and criminal law could also be considered as those areas might at present lack specific provisions needed to specifically adjudicate a neuroscience/neurotechnology case.

5. Consider specific data transfer arrangements

When laws outside of the Parties of Convention 108+ might not ensure an appropriate level of protection yet, policy makers and regulators should consider specific neuroscience or neurotechnology data transfer arrangements. Such arrangements could be built on existing pre-approved standardized contractual clauses¹⁰, 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 conducts, certification, etc.). All cross-border data transfers must comply with Art. 14 of Convention 108+ and be accompanied by appropriate safeguards to prevent misuse, unauthorized access, and privacy risks. 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 cross-border data exchanges must ensure that human rights, including privacy and human dignity, are not undermined.

6. Protect Minors and Individuals belonging to Vulnerable Groups

¹⁰ Reference to MCC

The impact of neurotechnologies and the processing of personal data related to minors and individuals belonging to vulnerable groups should be duly considered by policy makers and regulators. In particular, the following recommendations might also be considered: a) Prohibit neuromarketing, behavioral profiling, or manipulative uses targeting children or vulnerable individuals including with cognitive impairments. b) Require ethical reviews and age-appropriate legal basis/bases (such as consent/assent procedures) for research or permissible commercial use involving minors. c) Introduce special safeguards for vulnerable adults, ensuring that the legal basis or bases is/are valid with the appropriate support for decision-making where needed.

7. 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 legislation. They will increasingly play an important role in international enforcement cooperation based on Article 17 of Convention 108+ too, so they must be adequately empowered and properly resourced. These considerations seem to have special meaning when dealing with new technologies such as neuroscience or neurotechnology. Chapter IV of Convention 108+ on Supervisory authorities could be used as a reference in creating new powers/competences for supervisory authorities regarding neuroscience and neurotechnology in the Parties and beyond.

8. Allocate Adequate Resources:

It is highly recommended to ensure that supervisory authorities are well-funded, staffed, and trained to oversee neural data processing activities effectively, also in view of building specialized teams with expertise in neurotechnologies and mental privacy to address the unique challenges posed by neural data.

9. Ensure Operational Independence:

The independence of supervisory authorities from external influences, meddling, interference, pressures, including data controllers, processors, or public entities must be ensured in accordance with Article 15.5 of Convention 108+.

10. Promote Cross-Border Cooperation:

Supervisory authorities should promote collaboration with international counterparts to ensure consistent enforcement of neural data protection laws, particularly in global research and data transfer contexts.

11. Facilitate inclusive dialogue:

Structured mechanisms to engage with relevant stakeholders, particularly vulnerable populations and underrepresented groups, should be established to ensure responsive and inclusive regulation.

12. Consultative Role in Law and Policy

Under Article 15(3) of Convention 108+, Parties are to consult supervisory authorities on legislative or administrative measures relating to personal data. Supervisory authorities must be engaged from the earliest stages of neurotechnology-related policymaking to ensure human rights are embedded by design.

13. 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. These opinions may inform national legislation or sectoral codes of practice.

14. Awareness Raising and Public Engagement

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.

15. Stakeholder Collaboration

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

16. Participation in Human Rights Impact Assessments

Privacy Impact Assessments are a compulsory accountability obligation according to article 10 of Convention 108+ for data controllers; all guidance and cooperation from Supervisory authorities are to be encouraged in this area. Supervisory authorities are also invited more specifically related to neuroscience and neurotechnology to support or co-lead Human Rights Impact Assessments (HRIAs), including expanded Mental Data Protection Impact Assessments (MDPIAs), to ensure comprehensive risk evaluation and mitigation in neurotechnology design and deployment. They are also invited to actively engage in discussing and developing an internationally recognized methodology, such as HUDERIA.

17. 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 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 privacy, mental autonomy, cognitive integrity and other human rights related considerations into the design, development, and deployment of neurotechnologies.

It is of primary importance to carry out the Privacy Impact assessment (PIA) as foreseen by Article 10 of Convention 108+ which could also be tailored to the specificities of neuroscience and neurotech to specifically assess and mitigate risks to the rights and fundamental freedoms of data subjects, including privacy, human dignity, cognitive integrity and autonomy at every stage of product development if mental data is sought to be processed in a neuroscience environment or otherwise by neurotechnology. Such assessment could be followed by Human Rights Impact Assessments (HRIAs), including expanded Mental 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 HUDRERIA).

These assessments are recommended to be carried out in a way described in Chapter II by I. developers, manufacturers and service providers even if they do not participate directly in the policy making process.

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 strict purpose limitation, access restrictions, and independent oversight mechanisms.

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 outcomes¹¹.

¹¹ Poss: reference to AI Framework Convention for other conditions that need to be looked at and ensured

2. Fair, Transparent and Sustainable Data Practices

Transparency is an obligation under privacy 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.

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 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.

3. Safeguarding Neural Data

Cybersecurity considerations in today's digital world are key for private but also for public interest reasons as those databases may contain very sensitive information on individuals in a country that might be sought after by adversaries, cyber criminals. It is therefore paramount to adopt state-of-the-art security measures: to implement advanced cybersecurity protocols to prevent unauthorized access, breaches, or misuse of neural data. This includes among others strong encryption, secure storage, user credential distribution, logging and regular security audits.

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

4. Oversight and Internal Accountability

Developers, manufacturers and service providers of neuroscience and neurotechnology are strongly recommended to establish internal governance frameworks: a) Create dedicated governance teams or ethics committees. b) to put in place a data protection function to oversee compliance with data protection laws and human rights standards in neural data processing. c) to conduct independent audits: Engage 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 of vulnerable individuals without rigorous safeguards and legal basis. Implement grassroots level safeguards tailored for minors, persons with cognitive impairments, and other vulnerable groups, including simplified information, adequate support for providing consent, and strict profiling restrictions.

6. Collaboration and Standard Setting

It follows from recommendations of Chapters I and II that engaging with stakeholders, involving civil society, researchers, affected communities, and policymakers throughout development and deployment phases is of prime importance.

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 ethics¹².

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 Mental data Protection Impact Assessments.

If operations expand on several jurisdiction cooperation with regulators internationally is highly recommended just as well as the dissemination of best practices on integrating findings into system improvements.

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10.4 [ADDITIONAL RECOMMENDATIONS FOR FACILITATING NEUROSCIENCE RESEARCH AND INNOVATION

Neuroscience research offers substantial societal and medical benefits. To ensure that data protection regulations enable innovation without compromising individual rights, policy frameworks should actively support responsible research practices, especially in projects involving neural data.

The following recommendations aim to create a balanced, enabling environment for neuroscience research:

¹² References (UN, OECD, UNESCO, CoE AI Framework Convention, Oviedo convention?)

- **Simplification of Ethical and Legal Procedures:** SDPAs should work closely with research institutions and clinical organizations to streamline ethical review and compliance procedures for neuroscience projects involving neural data. This includes developing standardized templates and processes to avoid delays.
 - **Expedited Approval for Low-Risk Studies:** Implement fast-track approval mechanisms for studies using non-implantable neurotechnologies or anonymized neural data, provided that adequate safeguards are in place to protect privacy.
 - **Researcher Support Programs:** Provide guidance and training for neuroscience researchers on data protection requirements to foster compliance without stifling innovation.
 - **Clear Guidelines for Secondary Use of Data:** Establish clear frameworks for the secondary use of neural data in research to expand datasets for scientific discovery while respecting the original consent terms.
 - **Collaboration with Research Stakeholders:** Facilitate dialogue between SDPAs, neuroscientists, and healthcare professionals to ensure that regulatory frameworks reflect the practical needs of neuroscience research and do not create unnecessary barriers.
 - **Data Sharing Protocols:** Encourage the development of secure data-sharing platforms and protocols that allow neuroscience research institutions to collaborate while adhering to data protection standards.
- Facilitation of Cross-Border Studies:** Support cross-border neuroscience research by harmonizing data protection standards and promoting international agreements that enable secure data transfer while respecting privacy regulations. This includes establishing mutual recognition agreements for ethical approvals to prevent duplicate reviews.
- **Transparency and Public Trust:** Engage in public information campaigns to raise awareness about the societal benefits of neuroscience research, fostering public trust and participation.]