

Strasbourg, 21 October 2024

T-PD(2024)2

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

CONVENTION 108

**Draft Guidelines on the use of Neurotechnology and Neural Data from the Perspective
of Convention 108**

www.coe.int/dataprotection

Introduction & Content

Neurotechnology is an overarching term that encompasses a broad range of devices, tools, systems, and algorithms designed to understand, influence, monitor, access, assess, emulate, simulate, or modulate the structure, activity, and function of the nervous systems in humans and other animals. These technologies represent significant advancements in neuroscience, enabling unprecedented insight into neural functions and offering new ways to interact with neural processes.

The field of neurotechnology includes a wide variety of innovations, among which neural interfaces (NIs) stand out as one of the fastest-growing and most disruptive subfields. Neural interfaces are devices placed either within or external to the nervous system, capable of recording, decoding, or stimulating neural activity. These interfaces can engage with both the central nervous system (CNS) and the peripheral nervous system (PNS). This capability raises essential considerations regarding the categorization of neural data, particularly in distinguishing whether such data should be classified as personal data or belong to other categories.

Neural Data: What It Is and Why It Matters

Data captured through neural interfaces is commonly referred to as "neural data." This type of data provides quantitative measurements regarding the structure, activity, and function of the nervous system—both central and peripheral—within a living organism. The ability to decode or modify neural data implies the potential to influence cognitive and emotional processes, which can, in turn, affect mental states. In this context, mental states are understood as collections of mental representations and propositional attitudes within the human mind, related to activities such as thinking, remembering, planning, perceiving, and feeling.

The unique properties of neural data, particularly in comparison to other forms of data, present distinct challenges when it comes to privacy. Neural data carries profound implications for human rights, especially concerning personal data protections.

Human Rights and Neural Data: Navigating the Legal Landscape

Given the sensitive nature of neural data and its potential to affect individual autonomy and privacy, it is crucial for states to ensure that individuals can fully enjoy their human rights. This includes the right to personal data protection, even when neural data is collected and utilized. The guidelines herein propose a set of actions that governments, developers of neurotechnologies, and entities employing these technologies should follow to address these concerns.

At the heart of these guidelines is the recognition that neural data presents unique privacy challenges. In light of Convention 108, a legally binding instrument dedicated to protecting individuals' privacy rights, it is imperative to analyze how the collection and use of neural data intersect with existing legal frameworks. Furthermore, these guidelines should not be interpreted as undermining or limiting the principles outlined in Convention 108 and its modernized version, Convention 108+.

By adhering to these guidelines, governments, developers, and other stakeholders can work together to protect the privacy rights of individuals while promoting the responsible and ethical use of neurotechnologies.

Convention 108 provides a robust framework for addressing the data privacy implications of neural data, highlighting the importance of protecting individuals' privacy rights while promoting scientific progress and innovation in neuroscience.

In conclusion, these Guidelines interpret the convention to adapt and to reflect the complexities of neurotechnologies.¹

¹ These guidelines build upon a 204 report by Eduardo Bertoni and Marcello Ienca, “The privacy and data protection implication of the use of neurotechnology and neural data from the perspective of Convention 108”, available at <https://www.coe.int/en/web/data-protection/-/the-privacy-and-data-protection-implication-of-the-use-of-neurotechnology-and-neural-data-from-the-perspective-of-convention-108> . This Draft also took into consideration the comments received during the Bureau Meeting, Venice, October 2024.

GUIDELINES

1. GENERAL RECOMMENDATIONS TO BE CONSIDERED IN THE USE OF NEUROTECHNOLOGIES UNDER THE FRAMEWORK OF THE CONVENTION 108 AND 108+ 7

1. Enforcement of fundamental Human Rights Protections 7
2. Prevention of Misuse and Unethical Applications 7
3. Non-Discrimination and Neurodiscrimination 8
4. Data Collection from Minors and Vulnerable Groups 8

2. RIGHTS OF DATA SUBJECTS 9

1. Right to Access and Control Neural Data 9
Individuals are entitled to exercise free control and self-determined action over their neural data and mental information
2. Right to Rectification 9
Individuals have the right to obtain confirmation of their neural data being processed. Individuals have the right to obtain information about why their neural data is being processed and where the results of that processing are being applied.
3. Right to Erasure (10
 - Individuals have the right to request the erasure of neural data being used inconsistently with the provisions of the convention. If the controller refuses, “some remedy” should be made available to the individual.
4. Right to Object and Restrict Automated Processing 10
Individuals are entitled to not be subjected to significantly impactful decisions based solely on automated neural data processing without considering their views → Automated processing in respect to non-medical uses needs closer scrutiny as the justification for the impact on individuals via ADM may be much harder to justify. This issue is critical for closed-loop systems used for advisory and/or neuromodulation purposes (UK DPO Report). Individuals have the right to object to the processing of neural data unless the controller has a legitimate ground for processing that is more important than the individual’s rights or fundamental freedoms.
5. Right to Data Portability 10
6. Special Protections for Minors and Vulnerable Groups 11
7. Direct Reference to Convention 108+ 11

3.- GUIDELINES FOR LEGISLATORS AND DECISION MAKERS 12

1. *Scope* 12
2. *Applications of Neurotechnologies* 12
3. *Concepts and Definitions* 13
 - 3.1. *Neurotechnology* 13
 - 3.2. *Neural Interfaces – Motor, Sensory, Cognitive* 13
 - 3.3. *Neural Data* 13
 - 3.4. *Mental States – Cognitive, Affective, Conative, Perceptual, Sensory* 13
 - 3.5. *Mental Data and Cognitive Biometric Data* 14

- 3.6. *The Problem of “Mind-Reading”* 14
- 4. *Protection of Human Rights in the Design, Development, and Use of Neurotechnologies* 15
 - 4.1. *Multi-level Governance* 15
 - 4.2. *Protection of Minors and Vulnerable Individuals* 15
- 5. *Legal Basis for the Use of Neurotechnologies* 16
 - 5.1. *Consent* 16
 - 5.2. *Fairness* 16
 - 5.3. *Transparency (Procedural vs Algorithmic)* 17
 - 5.4. *Efficacy* 17
 - 5.5. *Accountability* 17
 - 5.6. *Accuracy* 17
 - 5.7. *Safety* 18
 - 5.8. *Purpose Limitation* 18
 - 5.9. *Necessity and Proportionality* 18
 - 5.10. *Exceptions and Special Circumstances* 19
 - 5.11. *Neural Data Collection* 19
- 6. *Neural Data Transfer: Safeguards* 20
- 7. *Mental Data Protection Impact Assessments (MDPI)* 20
- 8. *Supervisory Authorities* 21
- 9. *Raising Awareness* 22

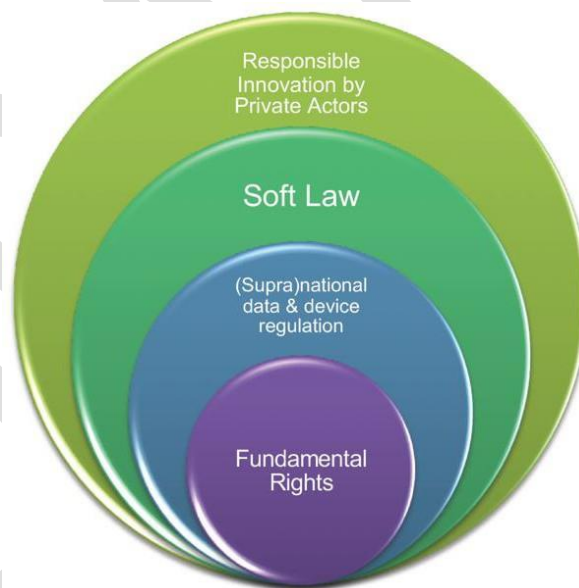


Figure 1- Multi-level Governance of Neurotechnology (re-used with acknowledgment from Ienca 2021)

4.- GUIDELINES FOR DEVELOPERS, MANUFACTURERS, AND ENTITIES USING NEUROTECHNOLOGIES 23

- 1. **Ethical Framework** 23
 - 1.1. *Exceptions to Ethical Requirements* 23
 - 1.2. *Addressing Neurodiscrimination* 24
- 2. **Responsible Innovation** 24
- 3. **Fostering Scientific Collaboration** 25
- 4. **Enabling Societal Deliberation** 25

5. **Promoting Cultures of Stewardship and Trust Across Public and Private Sectors** 26
6. **Quality of Data** 26
7. **Data Security** 26
 - 7.1. Anticipating Neurodiscrimination 26
 - 7.2. Limiting Neural Data Storage 27
 - 7.3. Data Security in Virtual Realities and Metaverse 27
8. **Data Storage** 28
9. **Data Sharing** 28

DRAFT