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Article

Neurodata and its protection from Artificial Intelligence and Neurotechnologies

Os Neurodados e sua proteção frente à Inteligência Artificial e às Neurotecnologias

Los Neurodatos y su protección frente a la Inteligencia Artificial y las Neurotecnologías

Isabel Cornejo-Plaza¹

Universidad Autónoma de Chile, Santiago.

<u>https://orcid.org/0000-0002-7409-0251</u>
<u>isabel.cornejo@uautonoma.cl</u>

Roberto Cippitani²

Universidad Nacional de Educación a Distancia, Madrid. Consiglio Nazionale delle Ricerche, Firenze, Italy. <u>https://orcid.org/0000-0002-0615-2713</u> <u>roberto.cippitani@unipg.it</u>

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Abstract

Neurodata, i.e. data from the examination of human brain activity and the nervous system, can be collected by different neurotechnologies with the use of Artificial Intelligence both in the medical field, from the diagnostic point of view especially through electroencephalography, brain-computer interface, functional magnetic resonance imaging etc., but also in health therapies and rehabilitation activity; in marketing and consumer services (e.g. video games and other entertainment applications), in applications for security purposes, to their use in criminal prosecution or for military purposes. This research attempts to elucidate from a legal point of view the nature and scope of neurodata with special emphasis on the question whether they can be considered as personal data or whether a specific regulation such as the Chilean one is necessary.

Keywords: Neurorights; Neurodata; Neurotechnologies; Personal data protection; Artificial intelligence.

Resumo

Os neurodados, ou seja, os dados provenientes do exame da atividade cerebral humana e do sistema nervoso, podem ser coletados por distintas neurotecnologias com o uso de inteligência artificial, tanto no âmbito médico, sob o ponto de vista diagnóstico, especialmente por meio de eletroencefalografia, interface cérebro-computador, ressonância magnética funcional, etc., como também em terapias de saúde e na atividade de reabilitação; no marketing e na prestação de serviços aos consumidores (por exemplo, em videogames e outras aplicações lúdicas), em aplicações com fins de segurança, até seu uso em processos penais ou para fins militares. Esta pesquisa busca esclarecer, do ponto de vista jurídico, a natureza e o alcance dos neurodados, com especial ênfase na questão de saber se podem ser considerados como dados pessoais ou se é necessária uma regulamentação específica, como a chilena.

¹ Phd in Law, Universidad de Chile, Santiago, Chile. Director of the research group pn Neuro-rights, Neuroethics, Artificial Intelligence, Metaverse and Economic Behavior (Neurometa) at the Law Research Institute of the Universidad Autónoma de Chile. Coordinator of the Jean Monnet e-Ride Module.

² PhD in Law and Economics, Sapienza University of Rome, Roma, Italia. Co-Director of the ISAAC Chair at the Universidad Nacional de Educación a Distancia, Madrid, Spain. Associate Researcher at the Consiglio Nazionale delle Ricerche, IFAC, Firenze, Italy.

Palavras-chave: Neurodireitos; Neurodados; Neurotecnologias; Proteção de dados pessoais; Inteligência artificial.

Resumen

Los neurodatos, es decir los datos provenientes del examen de la actividad cerebral humana y del sistema nervioso, pueden ser recolectados por distintas neurotecnologías con uso de inteligencia Artificial tanto en el ámbito médico, desde el punto de vista diagnostico especialmente mediante electroencefalografía, interfaz cerebro-computador, resonancia nuclear magnética funcional etc., pero también en la terapias sanitarias y en la actividad de rehabilitación; en el marketing y en la prestación de servicios a los consumidores (por ejemplo los videojuegos y otras aplicaciones lúdicas), en aplicaciones con fines de seguridad, hasta su uso en el proceso penal o con fines militares. Esta investigación intenta dilucidar desde el punto de vista jurídico la naturaleza y alcance de los neurodatos con especial énfasis en la pregunta si pueden considerarse como datos personales o si es necesaria una regulación específica como la chilena.

Palabras clave: Neuroderechos; Neurodatos; Neurotecnologías; Protección de datos personales; Inteligencia artificial.

Neurodata: Concept and Characteristics

Neurodata and its regulation has aroused global interest, as evidenced by the efforts of UNESCO, which this year has drafted a normative proposal with a content based on principles and values in the use of neurotechnologies. In this guideline, it is stated that neurodata:

These are quantitative data on the structure, activity and function of the nervous system of a living organism. They encompass data concerning the activity of a nervous system, including both direct measurements of neuronal structure, activity and/or function (e.g., neuronal firing or summed EEG bioelectrical signals) and indirect functional indicators (e.g., blood flow in fMRI and fNIRS). At the neurobiological level, neural data are the most direct correlates of mental states, as all cognitive and affective activity is primarily processed in the nervous system. Therefore, the prospect of decoding or modifying neural activity implies the possibility of decoding or modifying cognitive and affective processes.^(1, p.5)

In turn, the category of a subclassification of biometric data, where neurodata would be the species and cognitive biometric data the genus, is interesting and novel. The UNESCO Draft Regulation on the Ethics of Neurotechnologies defines it as follows:

Neural data, as well as other data collected from a given individual or group of individuals through other biometric and biosensor data, can be processed and used to infer mental states, which we describe herein as 'cognitive biometric data'. The processing of neural and other biosensor data, especially if supported by AI techniques, can enable inferences about cognitive, affective and conative states (hereinafter referred to as 'mental states') of the individual. Thus, cognitive biometric data includes not only neural data, but also inferences about mental states made by processing other biosensor data.^(1, p.5)

Neurodata from the examination of human brain activity and the nervous system can be collected by different neurotechnologies both in the medical field, from the diagnostic point of view especially by electroencephalography (EEG) but also in therapy and rehabilitation activity (as in the case of language)⁽²⁾; in marketing and in the provision of services to consumers (e.g. video games and other recreational applications), in applications for security purposes, up to their use in criminal proceedings or for military purposes.

Especially in the commercial field, devices that use brain interfaces and collect neurodata, such as Emotiv or Neurosky, or that announce a commercialization in the market of neurotechnologies, such as Facebook⁽³⁾, or Elon Musk's "Neuralink"⁽⁴⁾ are traded.

Such data have to be interpreted to predict future user behaviors, mental or brain states and other aspects of activity related to the people to whom the information refers⁽⁵⁾.

According to the specialized literature, it is now possible to identify age, sex, and even sexual orientation from brain activity⁽⁶⁾. Perhaps other information will be obtained in the future by examining neurodata such as guilt⁽⁷⁾ or political leanings⁽⁸⁾. Furthermore, in today's seemingly science fiction scenarios, such as in Steven Spielberg's film Minority Report based on Philip Dick's novel, brain data could be used to read a person's thoughts and predict their intentions⁽⁹⁾.

Neurodata as personal data

The aim is to understand how to qualify this type of data from a legal point of view.

A first possibility is to consider neurodata as personal data and therefore subordinate it to personal data protection disciplines, such as the European Union Regulation n° 2016/679 (here in after "GDPR") or analogous legislations.

The aforementioned regulations apply when the data are personal, and therefore when they allow the identification of a specific natural person (see art. 4, no. 1, GDPR). For the OECD - Organisation for Economic Co-operation and Development⁽¹⁰⁾, data derived from neurotechnologies are "data relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health, or mental states".

However, from a technical point of view, neurodata does not always directly allow the identification of its owner, but is usually a mere collection of information on the electrical activity of the brain and nervous system, which requires an interpretation of these for the identification of the person in question.

But Article 4, n° 1, GDPR, on the one hand, admits the identification of the person in an indirect way, i.e. in connection with other data. The definition used by the GDPR is very broad, due to the purpose of the protected interest that can be considered a fundamental right in European Union law (see Article 8 of the Charter of Fundamental Rights of the EU) and in other legal systems such as in some Latin American countries where the "habeas data" is recognized⁽¹¹⁾.

Indeed, as the Court of Justice states:

[...] the use of the expression 'any information' in the definition of the concept of "personal data" [...] is evidence of the Union legislator's aim to give this concept a very broad meaning, which is not confined to confidential or privacy-related data, but may cover any kind of information, whether objective or subjective, in the form of opinions or assessments, provided that they are 'about' the person concerned.⁽¹²⁾

On the other hand, if non-identifiability depends on considerations of a technical nature, it should be noted that identification may be carried out at successive moments and by other subjects as stated by the Court of Justice in the Breyer judgment where, in interpreting the term "indirectly", it is stated that "in order to determine whether a person is identifiable, one must consider all the means which may reasonably be used by the controller or by any other person to identify that person"⁽¹³⁾.

In addition, the aforementioned Article 4, n° 1, GDPR considers identifiability at the time of processing and not at the time of collection.

Therefore, information that today would not be associated to specific persons could be associated to them as a consequence of the evolution of the technique. An analogous case has been the human biological material preserved in collections formed, for medical diagnostic reasons for example, in times when there was no possibility of identifying, if not with the association of name and surname, to whom a tissue sample could belong⁽¹⁴⁾. Today this identification is possible and therefore makes this material contain personal data and therefore conflicts with the application of the discipline of personal data. Therefore, neurodata have a dynamic content of information (being an evolving technology), in the sense that it is not easy to distinguish how in the following years it will be possible to read the same set of data and which could be disaggregated.

Another question is whether neurodata can be considered as "special category data", provided for by Article 9, paragraph 1, GDPR, of which processing is prohibited, if not in specific cases, such as health processing or in the framework of scientific research.

Neurodata are not foreseen as special categories of data by Article 9 GDPR.

But they can be considered as health-related data, when they derive from medical diagnostic activities, or as biometric data. Biometric data are those obtained from a specific technical treatment, related to the physical, physiological (e.g. facial recognition, fingerprints, finger geometry, iris recognition, vein recognition, retina scanning), or behavioral characteristics of a physical person (e.g. handwriting patterns or the way of walking) with which the unique identification of that person can be formed⁽¹⁵⁾. Biometric data have uses in various fields, such as education, health, public and private security, commerce and neuromarketing, etc.

In the specific case of neurodata, these can also be collected in contexts very different from the previous genetic and/or genomic biometric data.

In the specific case of neurodata, these can also be collected in contexts very different from the previous genetic and/or genomic biometric data.

However, if one considers that the category of special data is constructed to protect the individual from a potentially discriminatory use of particularly sensitive information from the personal sphere, neurodata can be considered in this way. In fact, neurodata contain a representation of psychic activity, both conscious and subconscious, and correspond to the most intimate aspect of human privacy⁽¹⁶⁾.

Indeed, much of this information may only be relevant to its owner and if disclosed without consent may violate fundamental human rights such as the right to privacy and/or mental integrity and intimacy, as well as the right to identity⁽¹⁷⁾.

The fact that neurodata are not explicitly provided for in Article 9, paragraph 1, GDPR should not be considered an obstacle on the grounds of their identification within the category of biometric data and therefore be protected as a fundamental right of the individual.

This can be interpreted analogously in relation to the experience of genetic data which was not initially foreseen in the European discipline of personal data protection, but which qualified interpreters considered sensitive data⁽¹⁸⁾.

Therefore, the need to protect a fundamental right makes it advisable to consider neurodata as personal data and, in particular, a special category of biometric data, which deserve special forms of protection, since they concern sensitive aspects of people's lives.

Another relevant aspect arising from neurodata protection is the possibility of anonymizing neurodata. Although the link of neurodata to the civilian identity of an identifiable individual can be broken (in the sense that one could destroy the name at the top of a neurodata file and leave only the raw data), the data is still a unique representation of that particular individual and could be matched to other databases that do not provide for anonymization of the data, and in theory individualization of the data owner could be achieved.

Finally, neurodata present certain novel features compared to conventional forms of data.

A similar conceptual and contextual discrepancy was recognized in relation to the difference between genetic data and the data protection framework, and led to calls for "genetic exceptionalism"⁽¹⁹⁾.

Even when neurodata can be qualified as personal data, the special characteristics of these data are not sufficiently recognized by the current legislation on personal data protection.

Regulating other issues arising from the use of neurodata

The regulations on the protection of personal data do not cover all the ethical and legal aspects arising from the use of neurodata because, as mentioned in the previous paragraph, neurodata are not necessarily personal data, or at least may not be personal data to date.

Moreover, the legal protection of personal data takes into consideration the specific and isolated data and not the information elaborated from such data. In virtual reality, for example, the problem does not arise from the isolated data, but from the set of data, of diverse nature, provided by the immersive experience and processed with artificial intelligence systems. The central risk of virtual reality is that it directly provides a complete and dynamic profile of the individual.

It should be added that the operation of neurotechnologies can add other types of problems and affect rights other than those provided for in the GDPR or in personal data protection legislation.

For example, one of the great challenges presented by the use of technologies and especially neurotechnologies can be found in the area of consumer rights protection⁽²⁰⁾. European legislation (see Article 4, paragraph 2, letter f) of the Treaty on the Functioning of the European Union, hereinafter "TFEU") and that of many other countries identifies and protects natural persons as consumers of goods and services, as weaker subjects than professionals/entrepreneurs⁽²¹⁾. Legislation deals with consumers, mainly in two aspects (see mainly Article 38 of the EU Charter of Fundamental Rights and Articles 114 and 169 TFEU): firstly, the protection of consumer health (see in the EU Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety) and secondly the protection of their economic interests. Both interests can be jeopardized by inappropriate use of neurotechnologies, for example in the case of damage caused by malfunctioning of a technical device or non-consensual use of the user's information for purposes other than those envisaged in the contract.

In addition, the doctrine has pointed out that this type of technology can cause security problems⁽²²⁾.

Another problematic aspect can be associated with the use of neurotechnologies and neurodata by means of artificial intelligence systems, such as, for example, the one declared for this purpose by the company Neuralink.

From a security perspective, it should be recalled that Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonized rules on AI (the "Artificial Intelligence Regulation" or "Artificial Intelligence Act") implicitly refers to neurotechnologies and neurodata.

The Artificial Intelligence Act considers as "high risk" AI systems used by public authorities for law enforcement purposes that use biometric data, polygraphs or that detect the "emotional state"⁽²³⁾ of a person (see Annex III, para. 1, c) of the AI Act), with the consequent need to apply the specific rules provided by law, in terms of authorization and control.

Moreover, the preamble of the Regulation states that the classification of these systems as highrisk cannot be interpreted as legitimizing their use and placing on the market (see recital 63). On the contrary, the use of polygraphs or systems that detect the emotional state of persons may, except in limited and precisely defined situations, be used when strictly necessary to achieve an essential public interest whose importance outweighs the risks.

In addition, the AI Regulation establishes transparency rules in cases where: "AI systems intended to interact directly with natural persons are designed and developed in such a way that the natural persons concerned are informed that they are interacting with an AI system" (vid. Article 50 of the AI Act). The above is independent of the public or private subject using such systems, with the exception of criminal investigations.

Finally, it should be noted that the cited normative sources implicitly or explicitly refer to the need for the use of technology to respect the dignity of individuals, which also includes physical and psychological integrity, as well as the other fundamental rights at stake. The preamble to the Artificial Intelligence Regulation states that the rules laid down in that law "must be consistent with the Charter of Fundamental Rights of the European Union [and] must be non-discriminatory" (see recital 7).

In the field of neurotechnologies, in particular, it is necessary to consider the proposal of reconfigurations of human rights called "neuro-rights" such as cognitive freedom, mental integrity, psychological continuity or mental privacy, which have a sphere of protection beyond the protection of interests such as the protection of personal data or security⁽²⁴⁾. Indeed, the cognitive amplification of natural abilities through devices for commercial or recreational use that generate large amounts of neurodata, such as the brain-computer interface⁽²⁵⁾. Advances in neurotechnology and Artificial Intelligence have mainly given way to the regulation of mental indemnity, psychic integrity, mental privacy, decisions free of algorithmic bias, equity in access to cognitive augmentation technologies, and another series of taxonomic proposals that do not exhaust the proposal, but rather reinforce it⁽²⁶⁾.

As in other fields, especially those subject to the evolution of techno-science, for applications involving genetic data or human biological materials, neurotechnologies and neurodata are disciplined by different rules that regulate multiple aspects of a phenomenon that is complex and dynamic⁽²⁷⁾.

Specific regulations

The most recent global proposal on neurotechnologies is the current draft of UNESCO's Ethics of Neurotechnologies, 2024. This is a document prepared by special experts who have been tasked

with drafting a soft law instrument to serve as a normative and interpretative guideline in discussions related to neurotechnologies⁽²⁸⁾.

It seems logical to argue that neurodata needs a more specific normative approach.

In Europe, the European Parliament in a resolution of 2022⁽²⁹⁾ noted its concern about the lack of legislation on neurological data (paragraph 36), asking the Commission to present a legislative initiative on neuro-rights, to protect "the rights to identity, free will, mental privacy, equal access to advances in cognitive augmentation and protection against algorithmic bias" (paragraph 247). To date, this legislative initiative has not been submitted to the European legislator.

In Latin America, the "Parlatino" among its "Model Laws" has adopted in May 2023 the "Model Law of Neuro-rights for America"⁽³⁰⁾. In particular, the Model Law proposes:

To define that treatments that include brain imaging techniques and any other type of neurotechnologies that, based on data related to brain structure and/or functions, allow in some way to infer mental activity in all its aspects, may be used by court order and with the explicit and informed consent of the person, who must be previously informed about their characteristics, purposes and scope.^(30, p.6)

At the local level in Brazil, the bill that Amends Law n° 13,709 of August 14, 2018 (General Law on Personal Data Protection) has been presented, in order to conceptualize neural data and regulate its protection.

Chile has the most robust regulation of neurotechnologies, through the Chilean constitutional reform of neuro-rights and the draft law on the regulation of neurotechnologies, both of which place the protection of neurodata at their center, as can be seen in the phrase enshrined in the current fundamental charter that states the "protection of brain activity"⁽³¹⁾.

The purpose of this legislation is to enshrine the inclusion of the protection of brain activity, which can be interpreted as a true enshrinement of neuro-*rights as neurorights*, which implies that data extracted by certain neurotechnologies may cause damage to the fundamental rights of mental privacy and integrity, in addition to the identity of individuals⁽²⁴⁾.

The idea of legislating was approved unanimously in the National Congress in December 2020 (the parliamentary motions entered on 10-7-2020), both the bill on the protection of neuro-rights, mental integrity and regulating the development of research and the advancement of neurotechnologies, contained in bulletin 13.828-19 as well as the constitutional reform bill, which modifies article 19, number 1°, of the fundamental charter, regarding the protection of mental integrity and indemnity in relation to the advance of neurotechnologies, contained in bulletin 13.827-19.

The Constitutional Reform motion modifies the final clause of Article 19, number 1°, of the Fundamental Charter, to protect mental integrity and indemnity in relation to the advance of neurotechnologies, which becomes Law N°. 21.383, effective as of October 25, 2021, which states that:

Scientific and technological development shall be at the service of people and shall be carried out with respect for life and physical and psychological integrity. The law shall regulate the requirements, conditions and restrictions for its use on people, and shall especially protect brain activity, as well as the information derived from it.⁽³²⁾

For its part, the aforementioned bill on the protection of neuro-rights provides for the regulation of recreational neurotechnologies, establishing informed consent and adequate information as limitations to the inappropriate use of these technologies by their users.

This solution is adequate if one considers that the non-therapeutic uses of neurotechnologies can be risky for the health of people, and the collection of neurodata must be reinforced by the recent constitutional statute of neuro-rights⁽³³⁾.

This bill is currently in its second constitutional procedure in the Chamber of Deputies.

The Giradi/Emotive ruling of the Chilean Supreme Court

The need to adopt an appropriate legislative framework, not limited to the issue of personal data protection, arises from the controversial circumstance of the regulations applicable to neurodata and the discussion about their legal nature.

A first case that deserves particular attention is the recent judgment of August 9, 2023, folio n° 217225-2023 of the Supreme Court of Chile⁽³⁴⁾, which has decided on the constitutional protection action on behalf of Mr. Guido Girardi Lavín, against the company Emotiv Inc, which markets its Insight device (for Electroencephalogram monitoring without therapeutic purposes, which generates a huge flow of data, considered non-personal by the company because they are anonymized and for this reason it is impossible to individualize the user) in which it was denounced that the device in question did not adequately protect the privacy of the brain information of its users, violating the constitutional guarantees contained in numbers 1, 4, 6 and 24 of article 19 of the Political Constitution of the Republic of Chile.

In particular, the appellant claims that due to the use of the device and the storage of his brain information by the respondent company:

[...] has been exposed to risks that include: (i) Re-identification; (ii) Hacking of brain data; (iii) Unauthorized reuse of brain data; (iv) Commoditization of brain data; (v) Digital surveillance; (vi) Collection of brain data for purposes not consented to by the individual, among others.^(35, p.2)

In addition, it is noted in the appeal that "even though the Emotiv user account is closed, the respondent company retains brain information for scientific and historical research purposes"^(35, p.3).

Emotive pointed out that the brain data is not personal data, because since it is anonymized, it is not possible to identify its owner. In the meantime, the Emotive company performs legal acts on them, even though the holder is no longer using the device in question, relying also on the argument that the data holder consented, even beyond the object of the contract in question, allocating the user's neurodata for use in biomedical research. However, we know that informed consent in this area cannot be general.

The judgment clearly recognizes that the protection of neurodata is not only a matter of privacy. In fact, in the seventh paragraph of the judgment, referring to international sources and national legislation in the field of scientific research, the need for informed and specific consent of the persons involved in biomedical research is affirmed. Therefore: [...] the explanation of the respondent company, to the effect that the data it obtains from Insight users, upon being anonymized, become freely usable statistical information, omits as a prior matter the need to have the express, free and informed consent of its use for scientific research purposes, other than statistical registration, and expressly regulated in Chile by laws 20.120 and 20.584 and their respective regulations, in such a way that the information obtained for different purposes cannot finally have a different use without the owner's knowledge and consent. This also rules out that such consent can be considered tacitly given through other consents or approvals subscribed by whoever, as a client or consumer, acquires a certain device, requiring a specific consent that also indicates the purpose and end of the corresponding research.^(35, p.11)

Finally, in the eighth paragraph, it is recalled that:

In view of the development of new technologies that involve more and more aspects of the human person, -unthinkable a few years ago-, special attention and care must be given to their review by the State, in order to prevent and anticipate their possible effects, in addition to directly protecting human integrity in its entirety, including privacy and confidentiality and the rights of the psychic integrity and the subject of scientific experimentation.^(35, p.2)

Although the judgment is correct in addressing the issue of consent, it requires further development of the impact on the neuro-rights at stake, because although it invokes the right to mental integrity as part of the grounds for the motivation of the judgment, it does not delve into this and other fundamental rights such as mental privacy and cognitive freedom, and does not refer to why neurodata should be considered biometric data, beyond the distinction on their anonymization. The sentence remains with the mixture of nomenclatures between privacy, psychic integrity, which is an advance, but further dogmatic elaboration of the new reconfigurations of the same is needed, since these are the equivalents when we deal with the problem of the governance of neurotechnologies and brain data.

Another noteworthy point is that the judgment does not rule on the neurotechnological devices that are capable of neurophysiologically identifying an individual and, of course, does not refer to how their dissemination or transaction would affect the fundamental rights of individuals, and in this case the so-called neuro-rights.

In any case, this ruling constitutes the first of its kind and manifests a clear vision of protection and recognition of a new way of modeling certain emerging human rights in the face of the vertiginous advance of AI and related technologies.

Conclusions

Although brain data can be considered as a special category of data, in particular biometric data, therefore subsumable by data protection laws, they are not always exposed in the field of therapeutic and biomedical relationships, but exceed it, encompassing a collection of neurodata in the commercial and/or recreational virtual world.

In this respect, use without the user's consent could result in an unknown risk, which can only be speculated about. Information that allows the holder to peer into the processes of the human brain would be of significant value in a plurality of contexts in which one party seeks to influence or learn about another, especially when it allows better understanding and prediction of the actions of an individual or group of individuals. So far, outside of relatively limited laboratory or biomedical contexts, there have been significant practical obstacles to the use of neurodata.

First of all, a level of massification of the playful use of neurotechnologies has not been reached to make the collection of neurodata with which it works a practical problem of wider scope. However, in the face of the Girardi/Emotive judgment, we are reaching a point where the imagined scenarios overflow purely therapeutic applications where the use of neurodata is a reality in everyday and not merely medical contexts.

Secondly, advances in cognitive science are just beginning to provide the necessary knowledge and certainty to enable the practical use of this information. There has been a recent expansion of applications - for example, brain-computer interfaces. These applications collect neurodata as a prerequisite to their operation, providing the source and opportunity for further use⁽³⁵⁾.

Neurodata present certain novel characteristics compared to other data typologies and this, as we have seen, may lead to uncertainties and inadequacies in their application. We consider the possibility that, as neurodata represent interpretations of a given moment of a person's mind, such data may possess strong possibilities of prospective interpretation of the person, since it is an idea linked to the interpretation of mental states, physical, physiological identification and also linked to the idea of identity itself of the subject or ideas linked to *data dignity* or digital dignity, therefore the current level of protection offered by data protection legislations may be insufficient or inadequate.

Moreover, the protection of this type of data must take into account the various interests of the individual, which, as we have seen, are not limited to privacy. These are digital ecosystems where privacy is changing its role and challenges, seen that it is no longer understood as simple exclusion from others and where, on the contrary, people actively share their data⁽³⁶⁾. It is also important to consider that a specific law must be harmonized within a regulatory system that includes consumer law; fundamental rights; Artificial Intelligence; digital platforms; health statute, personal data, and neuro-rights among other systems that relate to vulnerable subjects such as childhood, old age, disability, indigenous populations etc.

Different disciplines can be applied to neurodata and neurotechnologies. In some countries, such as Brazil and Chile, a specific legislative framework has been adopted or is in the process of being adopted, while in the European Union there is still no concrete legislative proposal, although there is concern about the subject.

From the methodological point of view, the discipline of neurotechnologies, as well as of other new and future technologies, consists of a mixture of normative and non-normative approaches, in order to take into account the dynamic character of technoscience. From this point of view, an important role can be played by the use of flexible principles, which on the one hand constitute the expression of the normative-ethical system and on the other hand have the operational value of guiding interpretation.

For example, as the EU regulatory experience on artificial intelligence teaches, in addition to subject-specific regulation, it is useful to follow the technical and social changes associated with technologies, to use principles of a general nature of the legal and value system (dignity; self-determination; solidarity and protection of the weak; prevention and precaution; proportionality), and technology-specific principles (in the case of artificial intelligence: human intervention and surveillance; technical robustness and security; confidentiality and data governance; transparency;

diversity, non-discrimination and equity; social and environmental welfare; accountability, responsibility and liability)⁽³⁷⁾.

These principles are already emerging, albeit in a fragmentary manner, from the sources, case law and other documents mentioned above. The aim is to develop them and apply them to the subject of neurotechnologies.

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Conflict of interest

The authors declare that there is no conflict of interest.

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