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Advocating for neurodata privacy and neurotechnology regulation

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The ability to record and alter brain activity by using implantable and nonimplantable neural devices, while poised to have significant scientific and clinical benefits, also raises complex ethical concerns. In this Perspective, we raise awareness of the ability of artificial intelligence algorithms and data-aggregation tools to decode and analyze data containing highly sensitive information, jeopardizing personal neuroprivacy. Voids in existing regulatory frameworks, in fact, allow unrestricted decoding and commerce of neurodata. We advocate for the implementation of proposed ethical and human rights guidelines, alongside technical options such as data encryption, differential privacy and federated learning to ensure the protection of neurodata privacy. We further encourage regulatory bodies to consider taking a position of responsibility by categorizing all brain-derived data as sensitive health data and apply existing medical regulations to all data gathered via pre-registered neural devices. Lastly, we propose that a technocratic oath may instill a deontology for neurotechnology practitioners akin to what the Hippocratic oath represents in medicine. A conscientious societal position that thoroughly rejects the misuse of neurodata would provide the moral compass for the future development of the neurotechnology field.

A Protocol published in this issue[1] describes a neurosurgical procedure to perform high-density neuronal recordings from patients. The procedure details how to use a modified electrical probe[2] to record neuronal activity during tumor resections and deep brain stimulation (DBS) electrode placements in patients with Parkinson's disease. With this probe, the authors achieve the largest number of simultaneous recordings from neurons in humans to date. This technical and clinical feat will probably help shape future diagnostic and therapeutic approaches in the field of neurotechnology. Publication of this Protocol, its key reference article[3] and other recent literature[4–8] has provided timely opportunities to reflect on the evolution of neurotechnologies and their use in humans, in medical and nonmedical environments, with particular emphasis on their potential ethical and societal implications.

A path for neurotechnologies from the laboratory and the clinic to the consumer market

Neurotechnology can be defined as the ensemble of tools, methods and their associated devices for recording or modifying neural signals. These instruments operate by using electrical, optical, magnetic, acoustical or molecular signals and allow, in some cases, the alteration of the activity of the nervous system[9]. We can define two main classes of devices: those that need to be implanted and thus require neurosurgery and those that use external devices mounted on modified hats, helmets, headbands, glasses or bracelets and are thus classed as nonimplantable. Some of these devices, known as brain-computer interfaces, directly connect the central nervous system with a computer or an external machine[10,11]. Neurotechnology development was accelerated by the launch of the US BRAIN (Brain Research through Advancing Innovative Technologies) Initiative in 2013[12,13], a large-scale project to develop neurotechnologies for laboratory animals and human patients[14]. Similar initiatives have since followed in China, Japan, Australia, Canada, South Korea and Europe[15,16], in addition to multibillion-dollar investments made by private companies, and are cumulatively fueling the quick growth of the field[17].

Driving the interest and the investments in neurotechnology are its perceived scientific, medical and economic benefits. From a research

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perspective, neurotechnology tools and devices help neuroscientists explore the function of neural circuits and may help decipher how the activity of neuronal populations influences measurable aspects of daily life such as behavior, cognition and perception. Yet, neuronal activity also determines mental states[18], understood as the complex sum of experiences, memories and emotions that are harder to measure or quantify. Indeed, data obtained from optical neurotechnologies in mice have shown that ensembles of neurons acting in synchrony encode visual perceptions[19]. Manipulating these ensembles with holographic optogenetics—i.e., an experiment in which 3D neural activity patterns are activated in an animal brain by using a multiphoton holographic microscope—can generate false perceptions, similar to hallucinations, that the animal appears incapable of distinguishing from real visual cues[20,21]. These results, together with experiments in which the formation of artificial memories has been experimentally induced in mice[22], prove that, at least in a laboratory environment, the neural code that relates neuronal ensembles to behavior can be effectively decoded and manipulated by using neurotechnological devices.

From a medical perspective, research using neurotechnology[1] focuses on generating insights into the pathophysiology of brain diseases, including mental[23] and neurological[24] syndromes. These methods are expected to enable diagnoses with improved precision and cellular specificity, as well as to help develop new types of precision neurotherapies, in which neural circuits could be selectively targeted and modulated or reprogrammed. Indeed, several forms of implantable neurotechnology, such as DBS[25], and nonimplantable methods such as transcranial magnetic stimulation[26] are currently approved for use in Parkinson's disease, severe depression and substance-abuse disorders, among others. The main advantage purposed by the field is that these devices can bypass any defects or injuries in limbs and organs that transfer to the brain sets of complex sensory information, making it feasible, for example, to restore the perception of vision, hearing, tactile feedback or locomotion, but also to improve memory for neurodegenerative conditions or reduce the effect of traumatic experiences, thereby improving mental health.

In addition, from an economic perspective, and similarly to the explosive growth of biotechnologies[27] generated for the Human Genome Project, the neurotech industry[28] is gearing up for new economic opportunities, driven by the development of nonimplantable devices that can be directly sold to consumers for applications such as gaming, wellness, meditation or digital aids.

Recent advances in brain decoding with artificial intelligence

Neurotechnology enables, arguably for the first time, access to the activity of brain tissue, fulfilling the ancient desire to explore the neural correlates of the conscious and subconscious experience and define what, fundamentally, makes us human. Research using neurotechnologies often attempts, directly or indirectly, to question how reality is perceived and how perceptions vary, either as a result of a diseased state or as an individual response to a set of conditions. The answers to such questions also have the potential to reveal vast layers of sensitive information that we currently are not able to anticipate, because neurodata (i.e., the recording of the activity of the nervous system) can be generated subconsciously and often involuntarily. At the same time, while the potential benefits of neurotechnology are unquestionably many, we should also consider the ethical and societal consequences associated with its deployment in the clinic and its wider availability to the public. This is particularly salient because of the recent advances in decoding of brain activity in humans. For example, using implantable neurotechnology in paralyzed patients, speech can be effectively synthesized[29], and even attempted handwriting movements can be decoded[30]. Although the implantation of neural probes is a medical procedure governed by existing medical regulations and health data guidelines, ethical issues need to be urgently discussed because the decoding of brain activity by using noninvasive neurotechnologies is increasingly possible. For example, data obtained from functional MRI (fMRI) can be used to decode viewed images[31] and emotions[32,33] and correctly anticipate the interpretation of ambiguous narratives by a subject[34]. Moreover, the recent use of deep neural networks and latent diffusion models to analyze data acquired noninvasively has demonstrated that it is possible to decode the hearing of speech by using noninvasive electroencephalography or magnetoencephalography recordings[6] and decode semantic representation of images in the brain[5,7], as well as decode perceived speech, imagined speech and even silent reading[4] by using fMRI data. Finally, the use of nonimplantable transcranial alternating current stimulation[8] has enhanced working and long-term memory in adult volunteers, opening the possibility of neuroenhancement for nonmedical applications[35].

The accompanying ethical burden of neurotechnology

Like all technologies, neurotechnology is neutral and can be used for the benefit or detriment of the individual. Although fMRI, electroencephalography, magnetoencephalography and transcranial alternating current stimulation devices are normally restricted to clinical or research centers, the development of consumer devices in the neurotech space with continuous improvements in spatial and temporal resolution, together with the ease of use of artificial intelligence algorithms, raises ethical and societal concerns[36–38] because the ability to decode imagined images or speech jeopardizes mental privacy. A further concern worthy of note is mental integrity, because brain stimulation has the potential to alter personalities and behavior, as already reported in patients with Parkinson's disease using DBS[39,40]. A closely related issue concerns the effects of neurostimulation on human agency[41,42], defined as the capability to make free decisions and to be accountable for them. If neurotechnology is used to modify brain circuits involved in decision making, it is feasible that it could also diminish our agency and free will. These are issues that, from a legal and societal standpoint, have no precedent in history. The use of neurotechnology for mental and cognitive augmentation is also significantly complex because enhancing memory[8], enhancing attention spans[35] or potentially providing fast access to external databases and algorithms raises ethical issues, which include consent and the need to define who has, or will have, access to these technologies and their respective data[43]. It is also important to note that the algorithms used in neurotechnological devices run the risk of being biased against particular groups of people and could lead to discrimination, for example, in the workplace[43,44]. These issues potentially undermine the safe use of neurotechnological devices because, as already demonstrated in mice experiments[20], the brain of the animal interprets information encoded by an external device as its own subjective experience—i.e., the brain lacks the tools to separate, ignore or delete signals provided by external devices—and we currently do not understand the full and long-term impact that these stimuli may have.

Ethical guidelines and neurorights

In response to the growing neurotechnology field, guidelines could serve as a roadmap and as sets of guardrails for future development and deployment of neurotechnologies, while enabling their growth and dissemination (Fig. 1). International organizations, including groups of concerned academics, scientists, engineers and technologists, professional societies and national governmental bodies, including the Morningside and Brocher groups, the BRAIN Initiative Neuroethics Working Group, the Institute of Electrical and Electronics Engineers, the Organisation for Economic Co-operation and Development, Spain, the United Kingdom and the Council of Europe, among many others, have proposed sets of ethical guidelines for neurotechnologies[28,36–38,43,45–65], including recent reports from the United Nations Educational, Scientific and Cultural Organization[66] and the U.K. Information Commissioner's Office report[44], which widely converge on common points to ensure that safety and security standards are met (Fig. 2). However, it

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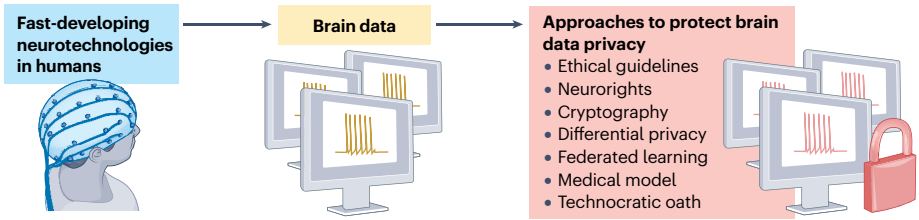

Fig. 1 | Potential approaches to protect brain data privacy. Complementary and synergistic approaches, such as ethical guidelines, human rights, technical solutions (including cryptography, differential privacy or federated learning) and medical regulations, could be deployed to ensure that decoding of neurodata happens only under strict privacy guidelines.

is useful to point out that ethical guidelines and recommendations are not legally binding; rather, they are examples of 'soft law' and are intended as complementary instruments to legislative frameworks. As such, they imply individual self-regulation and support by commercial stakeholders. To further support the voluntary uptake of these practices, a new category of human rights, termed 'neurorights', has been proposed to enhance the existing corpus of human rights, as the principal standards to maintain via international 'hard' law[38,43,61,67,68] (Fig. 1). Although some researchers question whether defining a new category of neurorights is adequate or even necessary[69–73], a recent report concluded that existing international human rights treaties lack the legal precision and even terminology to legally approach the technology or the ability to modify brain function and thus do not adequately cover neurorights[74].

As a positive outcome of these ongoing discussions, proposals for ethical guidelines and extensions of human rights have stimulated the development of national policies and legislation. A pioneer example is that of Chile, where both chambers of the Congress of the Republic unanimously approved in 2021 a constitutional amendment that protects 'brain activity and the information that comes from it' as a basic right of all citizens[75]. Chile's Senate also unanimously approved a neuroprotection bill that provides specific protection for mental privacy, individual identity and individual agency and guarantees fair access to neuroenhacement technologies[76]. Neurorights efforts in other countries include Spain's Charter of Digital Rights, which protects citizens from potential abuses of artificial intelligence and which also incorporates neuroprotection[77,78]; the Organization of American States Declaration on Neuroprotection and Human Rights[79]; and other declarations that discuss neurotechnology, such as the Council of Europe Strategic Action on Biomedicine[80], the United Nations Educational, Scientific and Cultural Organization Bioethics Committee declaration[81] and the Organisation for Economic Co-operation and Development Recommendation for Responsible Innovation Neurotechnology[82]. Finally, the Secretary General of the United Nations has singled out neurotechnology as an open human rights challenge[83], and the Human Rights Council of the United Nations has unanimously approved to undertake a study to explore the human rights aspects of neurotechnology[84].

Technical solutions to neurodata privacy

Perhaps the most urgent issue that needs immediate action is the protection of the privacy of neurodata, given the recent successful decoding of mental imagery, emotions, story interpretation and speech with nonimplantable devices[4–8]. The ability to decode words and images could lead to the decoding of mental activity, because the ability to think, reason and perceive mental states as feelings or emotions is often accompanied by images or language. Privacy issues for neurodata may therefore have much deeper consequences than those of most digital technologies[62]. As a complementary set of solutions to the development of ethical guidelines and neurorights, technical approaches could also minimize risks to breaches in neurodata privacy (Fig. 1). Data privacy is not a new problem, and the complex challenges of ensuring data privacy, data security and data sharing have stimulated new approaches for data protection within the banking, national security, health and clinical research fields. Indeed, data encryption is already used to protect data privacy. Cryptographic algorithms, like state-of-the-art homomorphic encryption, convert data into cipher text that can be analyzed as if it were still in its original form[85]. Thus, the use of encryption would ensure neurodata protection, while still allowing for its analysis, and a user consent request would need to be approved for any decoding to take place.

A different set of concerns worthy of note, and accompanying technical solutions, arises from the aggregation of neurodata, necessary for data mining and algorithms. Every time that data are shared or processed, the possibility of the data being aggregated with other personal information increases, thereby increasing the risk of the data becoming identifiable. To minimize this risk, differential privacy—i.e., a system for sharing information about a dataset by describing its group patterns while withholding information about individuals—could be valuable, because it allows the statistical querying of data while avoiding the disclosure of the identities associated with specific datasets[44,86,87]. One form of differential privacy is federated learning, which allows centralized algorithms to be trained off decentralized raw data. Thus, in federated learning, the raw data stay local to the device or secure database and are not shared with the learning algorithm; rather, the local device only sends query outcomes in the form of metadata to the centralized algorithm[88]. By never being shared with the centralized algorithm in the first place, federated learning environments would help maintain neurodata privacy and reduce risks of data identification[89].

Regulation of sensitive health data

One could argue that the problem with brain data is not new. Ensuring the privacy of neurodata mirrors similar concerns that the medical profession has successfully dealt with when ensuring the confidentiality and protection of patient information. Indeed, highly sensitive data are stored through electronic health records and research databases. Sharing of these data is beneficial for patients' clinical care and can also inform research that will do substantial public good. However, sharing data that include personal information and biological proclivities still poses a significant privacy threat. With data privacy becoming an increasing public concern, policies such as the Health Information Portability and Accountability Act (HIPAA)[90], the European Union's General Data Privacy Regulation[91,92] and the California Consumer Privacy Act[93] provide a regulatory framework for public and private enterprises, supported by data-sharing projects that promote patient privacy, such as the Observational Health Data Sciences and Informatics[94]. In fact, in most countries across the world, regulations are in place to provide similar levels of protection to patients' health records.

Existing procedures for managing health data are categorized in classification and aggregation. Data sensitivity classification is normally binary, because legal language used for legislative purposes needs to be clear and not open to interpretation, so personal data are either 'sensitive' or 'not sensitive', 'identifiable' or 'not identifiable'.

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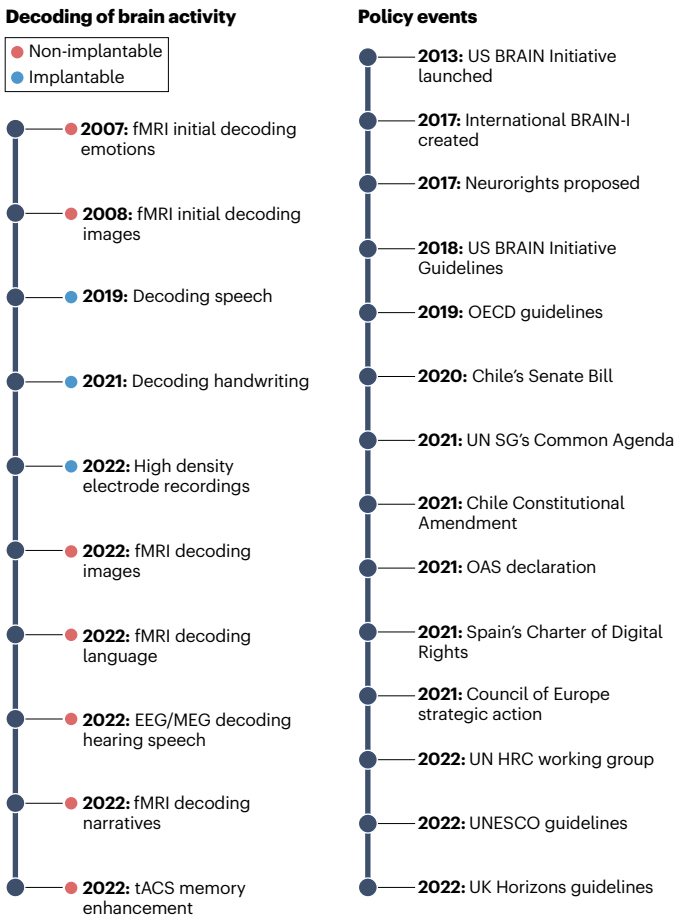

Fig. 2 | Developments in brain data decoding and neurotechnology regulation. Partial list (left) of recent milestones in the decoding of brain activity in humans with implantable or nonimplantable neurotechnology. Significant guidelines and policy events (right) related to neurotechnology. BRAIN, Brain Research through Advancing Innovative Technologies; EEG, electroencephalography; HRC, Human Rights Council; MEG, magnetoencephalography; OAS, Organization of American States; OECD, Organisation for Economic Co-operation and Development ; SG, Secretary General; UN, United Nations; UNESCO, United Nations Educational, Scientific and Cultural Organization.

Processing of sensitive data is consequently significantly stricter than that of nonsensitive data. However, there is little additional gradation between these two types of personal data[91]. Health data aggregation refers to the integration of multiple data sets to glean further insight into a specific group or subject. Aggregation is typically performed on data that are not sensitive or not identifiable; however, precisely because aggregation merges information from multiple datasets, successive rounds of aggregation may render that data sensitive or identifiable, depending on the information merged[95]. The data brokerage industry merges both public and purchased data to provide information insights such as individualized user profiles to stakeholders in industries such as marketing, law enforcement, health, insurance and education[96]. Although medical data must be de-identified before being sold according to HIPAA in the United States, data brokers add their own identifying numbers to collect records. This allows data brokers to connect additional data to a single piece of medical information, which ultimately renders de-identified information more identifiable[97]. This is a concerning prospect for neurodata because they can be acquired both within and outside of medical contexts, making it potentially easier to cross-correlate. Indeed, two different studies demonstrated that an algorithm was able to identify an American citizen with 99.98% accuracy on the basis of 15 attributes such as their gender or their incomplete zip codes[98], or with only their date of birth, zip code and gender[99].

A medical model for neurotechnology and neurodata

For neurotechnological devices used in clinical settings, existing approaches and regulatory frameworks for storing and handling sensitive health records already have procedures in place. In contrast, the collection or sale of neurodata in nonmedical contexts via direct-to-consumer neurotechnologies is not subject to HIPAA or, to our knowledge, specifically regulated by any other data privacy laws in the United States. Indeed, an ongoing survey of consumer user agreements of 18 neurotechnology companies finds that every company takes ownership of all collected neurodata, and 16 out of 18 hold the right to transfer the data to third parties, with freedom to decode, sell or even destroy them (Genser and Yuste, manuscript in preparation).

Devising specific regulations for the collection, storage and sharing of neurodata will probably take time and require a balancing act similar to that faced for health data management to maximize data sharing while minimizing breaches of privacy. As a practical solution to the regulatory void model, it has been proposed that neurotechnologies could follow the medical model and adopt the same regulations and procedures that are already in place for sensitive health data[36]. The advantages of this proposal are that the existing health regulatory framework that examines and approves the use of any medical device or pharmaceutical agent is already ubiquitously implemented, robust and extensive. Thus, instead of developing a new regulatory framework, one could redefine neurotechnology devices as medical devices, making them subject to approval and recommendation by the Food and Drug Administration, the Medicines and Healthcare Regulations Authority, the European Medicines Agency or similar public health organizations, as applicable to different countries. Importantly, a medical model would apply not just to implantable devices, but to all neurotechnology devices, including wearables and noninvasive modalities. Therefore, all devices capable of recording or altering neural activity, either directly or indirectly, and either from the central or peripheral nervous system, should be considered on a par for regulatory purposes. Although the consumer market for neurotechnology is still in its infancy, devices such as glasses, headsets, helmets, caps, bracelets and, even recently, ear pods[100] that incorporate neural recording technology are being developed and sold. As neurotechnologies become increasingly popular in consumer markets, this challenge becomes more urgent. Although the regulated sharing of neurodata could help improve patient management (e.g., by improving diagnosis and early therapeutic options as appears likely the case for patients suffering from Alzheimer's disease), this information could also be misused by companies for increased profits or by malicious actors.

Use of a medical model for neurodata could immediately limit its misuse; on the other hand, it could also constrain innovation, as layers of regulation on the fledging neurotechnology industry might lengthen developmental time frames. By definition, all regulation is constraining; yet, the existing medical regulations applied to the biomedical industry, while arguably not perfect, have not hampered innovation in the field. Indeed, biomedical companies are among the largest in the world and have navigated the regulatory landscape effectively while maintaining vibrant research and innovation portfolios. In addition, by guaranteeing high standards for neurodata safety, neurotechnology companies that operate under a medical model could benefit from being perceived as responsible and safe by consumers.

Adoption of a medical model for neurotechnology is being considered in different countries as a practical solution. In Chile, a neuroprotection bill (13828-19) passed by the Senate defines all neurotechnology as medical devices and applies to them the existing Chilean medical code, with regulatory approval by the national Public Health Agency[76]. This bill details a set of penalties and fines, in accordance with Chilean medical legislation, for companies, stakeholders, users or developers

that do not follow the medical regulatory procedures, while simultaneously providing ample provisions to foster the development and application of neurotechnology for medical and research purposes. Similar to the Chilean Senate bill, the UK Regulatory Horizons Council[101] also recommends categorizing all neurotechnology, whether implantable or not, as medical devices. Finally, a recent regulation by the European Union also defines as medical all nonimplantable brain-stimulation devices, albeit without mention of noninvasive recording[102].

A technocratic oath for neurotechnology

In medicine, besides the regulations that cascade top down from policymakers and legislators, there is also a bottom-up deontology adopted by medical practitioners. A paradigm of this is the Hippocratic Oath, attributed to Hippocrates (460–circa 370 BC), which although not legally binding, is morally binding. Its cores values ('do no harm') were incorporated into the principles of beneficence, justice and dignity of the Belmont Report that provides ethical guidelines for research with human subjects[103]. The Belmont Report itself has informed legislation in the United States and around the world that guides medical practice and the biomedical industry while protecting patients.

Similar to the Hippocratic Oath, and taking the medical model one step further, one could implement a 'Technocratic' Oath, as a personal, simple and easy-to-remember pledge that scientists, engineers and entrepreneurs developing and using neurotechnology in humans take upon their conscience to 'not cause harm'[104]. Once taken, this pledge is never forgotten and could also incorporate principles such as beneficence, dignity and justice. Example pilot programs of a voluntary technocratic oath have been explored at the Universidad Católica de Chile, and companies like IBM in the United States and Sherpa.ia in Spain[104].

Moving conscientiously forward

There is no questioning that neurotechnology can benefit science, medicine and society. Yet, because of its power to record and alter brain activity, these same methods expose human mental privacy and integrity to unforeseeable risks. The issue is complex and nuanced[63]. The regulation of medical devices and the protection of sensitive data are different issues that may benefit from multipronged approaches in different countries and at the international level. Nevertheless, within this complexity, we advocate erring on the side of caution and consider medical-standard approaches in the first instance to ensure the protection of neurodata and the ethical growth of this critical technology, while the wider community discusses in more detail the development of specific ethical guidelines and human rights approaches, as well as technical solutions that would minimize the risks to breeches of neural privacy.

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Competing interests

The author discloses his role as chairman of the Neurorights Foundation, whose goal is to promote research, advocacy and outreach on neurorights.

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