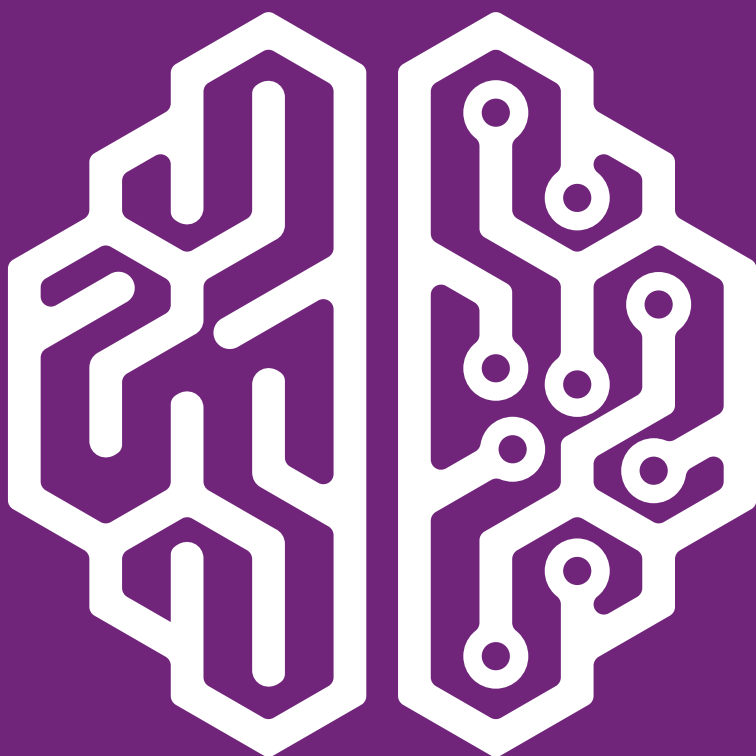




ETHICAL ISSUES OF NEUROTECHNOLOGY

REPORT • Adopted in December 2021

IBC International Bioethics
Committee of UNESCO

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SHORT SUMMARY

Should we be afraid of neurotechnology?

1 in every 8 people worldwide lives with a mental or neurological disorder (IHME, 2019), which represents 1/3 of health expenses in developed countries, and a growing burden in Low-to-Middle-Income Countries. With the potential to provide new treatments and preventative and therapeutic solutions, neurotechnology offers tremendous hope for patients around the world.

However, this technology raises unique ethical concerns. Unlike many other frontier technologies, neurotechnology can directly access, manipulate and emulate the structure of the brain, which is central to notions of human identity, freedom of thought, autonomy, privacy and well-being. The increasing possibilities to modify the brain, and consequently the mind, in an invasive and pervasive way, requires us to ask unprecedented questions. Is there a need for new neuro-specific human rights to protect our mental privacy and integrity?



The International Bioethics Committee of UNESCO identifies the benefits that may result from neurotechnology, but also the fundamental human characteristics and associated human rights that might be challenged by these developments. This Report puts forth concrete recommendations to a wide array of stakeholders, including UNESCO, Member States, the research community and the public.



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"Since wars begin in the minds of men and women it is in the minds of men and women that the defences of peace must be constructed"

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REPORT • Adopted in December 2021

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FOREWORD

From medication that improves quality of life to brain imaging that revolutionizes our conception of human consciousness, neurotechnology has the potential to redefine our understanding of who we are, and to leverage the power of the brain to improve well-being.

The sky is the limit for neurotech applications. In schools, they can improve learning. In day-to-day shopping, they can help connect our inner wishes to the products on the shelf. Computer power and possibilities could also be expanded, through features such as a thought-to-text writing, as well as virtual and augmented reality systems that are assisted by brain control for entertainment purposes.

But as with all technological developments, neurotech, if used unwisely can do more harm than good. As it actively interacts with, and alters the human brain, this technology also raises issues of human identity, freedom of thought, autonomy, privacy and flourishing. The risk of unauthorized access to the sensitive information stored in the brain is a case in point. Already today, neural data is increasingly sought after for commercial purposes, such as digital phenotyping, emotional information, neurogaming and neuromarketing. Neuromarketing units have been developed by industry to evaluate, and even alter consumer preferences - raising serious concerns about mental privacy. These risks can also pose serious problems when dealing with non-democratic governments.

With over thirty years of experience in global standard-setting and national capacity-building in the ethics of science and technology, UNESCO understands the critical role that bioethics can play in placing human rights and human dignity at the centre of this debate. For this reason, we welcome the new report on Ethical Issue of Neurotechnology, prepared by our International Bioethics Committee (IBC).

Continuing the tradition set by previous reports of the Committee, the Report on Ethical Issues of Neurotechnology breaks new ground in this domain, by presenting an in-depth analysis of the ethical, legal and regulatory implications of neurotechnology. Developed over two years, the Report has been enriched by the multidisciplinary and multicultural expertise of IBC's 36 members, each serving in their independent expert capacity.



This report dares to ask bold questions: do the existing human rights frameworks provide adequate safeguards against the risks emanating from an unfettered development and use of neurotechnology? Or do we need a new set of neuro-specific rights, such as the right to cognitive liberty, mental privacy, mental integrity, and psychological continuity, to protect human rights and human dignity from any adverse impact?

As with different emerging technologies, our experts also focus on how to maximize the positive impact of these scientific developments, while controlling the downsides. The message in this report is clear. We need to build a shared global understanding on the interactions between neurotechnology, ethics and human rights - just as we have done regarding the human genome and Artificial Intelligence in UNESCO. This is the only way to ensure that these technologies serve human needs and not the other way around.

We take to heart the advice these world-class experts provide us with, as the international institution in charge of ethics. We need to build a global consensus on the ethics of neurotechnology, on the basis of open discussions with all relevant stakeholders, all over the world. The new frontier on the ethics of neurotechnology requires strong leadership and political support from Member States, to ensure that human rights and dignity inform our efforts. The stakes are high, but our commitment to deliver is even higher. So, let's put all hands on deck to ensure technological developments deliver for good. We need to raise awareness, and all relevant stakeholders need to be engaged.

Gabriela Ramos

Assistant Director-General for Social and Human Sciences,
UNESCO

Within the framework of its work programme for 2020-2021, the International Bioethics Committee of UNESCO (IBC) decided to address the ethical issues of neurotechnology.

Following the online discussions of the Committee after the 26th (Ordinary) Session of the IBC in July 2019, the Committee established a Working Group to develop an initial reflection on this topic in February 2020. Due to the challenging situation posed by the COVID-19 pandemic, the IBC Working Group functioned primarily through email exchanges, and held two working group meetings in May and September 2020. As a result, a synopsis of the preliminary draft report was presented and discussed during the 27th (Ordinary) Session of the IBC in December 2020, which was held online with a condensed agenda. Furthermore, the preliminary draft report was discussed and presented during an extraordinary session of the IBC and the joint session of the IBC and the IGBC, which took place online in February 2021.

Taking into account the comments and feedback received during the above-mentioned sessions in February 2021, the IBC Working Group held an online meeting in June 2021 to prepare a final draft report, which was adopted by the Committee at its 28th Session in December 2021.

This document does not pretend to be exhaustive and does not necessarily represent the views of the Member States of UNESCO.

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INTRODUCTION



1. Brain activity is the basis of cognitive, affective and other brain states. Brain activity is so important to our life that, in many countries, death is legally defined by irreversible cessation of brain activity. Brain activity provides information inherent to all human beings regardless of gender, nationality, language or religion. The centrality of brain activity to notions of human identity, freedom of thought, autonomy, privacy, and human well-being means that the ethical, legal, and societal impact of recording ('reading') and/or modulating ('writing') brain activity through various devices and procedures collectively named neurotechnology¹ is of paramount importance. This report has been undertaken in light of the rapid development of the field and the IBC's mission to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications.
2. Throughout history, physicians have attempted to understand and treat diseases of the brain using various methods, beginning with trepanning or trephining in ancient times. There is evidence to show that this practice existed in ancient Egypt, Greece, Rome, West Asia and China, and this method was being used on many continents as late as the 18th century (Kandel et al., 2000). Neurological conditions such as epilepsy, migraine, brain tumours and encephalitis, and mental conditions such as depression and bipolar disorders, for which there were no apparent causes, were often attributed to divine punishment or demonic possession.
3. Advances in the understanding of anatomy and physiology, helped by microscopy and histology during the 18th century, led to the establishment of neurology as a major branch of medicine in the 19th century. The anatomopathological method initiated by Laennec² allowed clinical findings to be linked to post-mortem changes, and thus defined several neurological conditions. The discovery of neurotransmitters and their actions on the brain and peripheral nerves was initiated in 1878 when Claude Bernard described the nerve/muscle blocking action of curare. The next century saw the remarkable understanding of the chemical action in the brain and the receptor transmitter/inhibitor set-up, leading to the development of valuable drugs to combat a wide variety of neurological diseases, including hitherto untreatable psychiatric disorders.
4. While the electrical properties of nerves relating to action potentials and nerve impulse transmission at synapses had already been reported by Luigi Galvani, Guillaume Duchenne de Boulogne, Hermann Von Helmholtz and Charles Sherrington, to name just a few, the birth of neurotechnology may be dated to the demonstration by Hans Berger in 1929 that it was possible to record changes of electrical potential in the human brain with an electroencephalography device. This led to important advances such as the accurate diagnosis and treatment of epilepsies.
5. The chance discovery of X-rays by the physicist Wilhelm Rontgen in 1895 provided the first non-invasive internal view of the human body. More advanced, refined and safer

1 Neurotechnology: devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons (OECD, 2019).

2 Laennec (1781-1826) defined the anatomoclinical (or anatomopathological) method as 'a method for the study of pathological states based on the analysis of the observation of symptoms or alterations of functions that coincide with each species of organ alteration' (Laennec, 1837).

imaging techniques would be introduced in the latter part of the twentieth century – the ultrasound scan (1956), computerized axial tomography (1967) and magnetic resonance imaging (1980). These and newer technologies used to access, investigate and monitor brain structure and function would present ethical concerns not seen with the use of neuropharmacological drugs.

6. Neurotechnology is the field of devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of animals or human beings. These include: (i) technical and computational tools that measure and analyse chemical and electrical signals in the nervous system, be it the brain or nerves in the limbs. These may be used to identify the properties of nervous system activity, understand how the brain works, diagnose pathological conditions, or control external devices (neuro-prosthesis, 'brain machine interfaces'); and (ii) technical tools that interact with the nervous system to change its activity, for example to restore sensory input, such as cochlear implants to restore hearing or deep brain stimulation to stop tremor and treat other pathological conditions. They are meant to either record signals from the brain and 'translate' them into technical control commands, or to manipulate brain activity by applying electrical or optical stimuli.
7. Neurotechnology may be restricted to direct recording of human brain activity and/or direct influence/modification of brain activity, but it can also be seen more broadly as any device and/or application (apps, AI, big data, etc.) able to derive knowledge of an individual's brain activity and/or influence/modify an individual's brain activity. As such, neurotechnology is any technology that has a fundamental influence on how people understand the brain and various aspects of consciousness, thought, and higher order activities in the brain. It also includes technologies that are designed to improve and repair brain function and allow researchers and clinicians to visualize brain structure and function.
8. The present report will consider neurotechnology through health applications, as well as direct-to-consumer (DTC) neurotechnology (such as neurogaming, well-being devices, etc.), driver safety applications, education and any other field of application.
9. Brain disorders represent a major and increasing burden worldwide: one third of health expenses in developed countries (DiLuca and Olesen, 2014), and a growing burden in Low-to-Middle-Income Countries (LMICs) (Feigin et al., 2020). Brain disorders include neurological and mental disorders, some of the latter often called mental and psychosocial disabilities or mental impairment by patient organizations and by the United Nations Department of Economic and Social Affairs.³ Consequently, there is a need to provide new treatments and deliver better preventive and therapeutic solutions to millions of people suffering from neurological and mental illness. To this end, enhancing our scientific

3 *'Persons with mental and psychosocial disabilities represent a significant proportion of the world's population. Millions of people worldwide have mental health conditions and an estimated one in four people globally will experience a mental health condition in their lifetime. Almost one million people die due to suicide every year, and it is the third leading cause of death among young people. Depression is the leading cause of years lost due to disability worldwide. Mental health problems, including alcohol abuse, are among the ten leading causes of disability in both developed and developing countries. In particular, depression is ranked third in the global burden of disease, and is projected to rank first in 2030.'* <https://www.un.org/development/desa/disabilities/issues/mental-health-and-development.html>.

understanding of human brain function and unlocking the pathological conundrums of several treatment-resistant neurological and mental disorders is a major priority.

10. Investment in brain research has become extremely important, with a growing number of large-scale programmes aimed at developing technologies to intervene on the brain (IBI, 2016). In 2013, the United States launched the Brain Initiative, while the European Union launched the Human Brain Project. Japan, Korea, Australia, China and Canada have also developed major programmes on ‘cracking the brain’s code’, both to better understand its structure and mental processes, and to develop new technologies with, among other things, controlled robots, autonomous systems and hybrid technologies, in order to treat certain pathologies and to compensate for forms of disability.
11. ‘Neural data’ [also called ‘brain data’⁴] are becoming a sought-after data type and commodity beyond the medical sector (in particular, in the consumer market). Consumer neurotechnology, digital phenotyping,⁵ affective computing,⁶ neurogaming⁷ and neuromarketing⁸ are some of the domains where this vision of neural data as a commodity is highly valued. This increasing extra-medical availability of brain data raises a challenge for ethics and for human rights, and obviously requires governance. Risks include re-identification, hacking, unauthorized reuse, asymmetric commodification, privacy-sensitive data mining, digital surveillance, trading-rights-for-services, co-optation for non-benign purposes and other misuses.
12. At the time of the present report there are few regulations on neurotechnology outside of regulation of medical devices used in the medical field or in the field of scientific research, though some countries are currently developing new legal instruments.^{9 10} Significantly, the Organization for Economic Cooperation and Development (OECD) Council adopted the

4 Personal brain data: 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 (OECD, 2019). In this report we define neural data as personal brain data.

5 Digital phenotyping was defined by Jukka-Pekka Onnela in 2015 as the ‘moment-by-moment quantification of the individual-level human phenotype *in situ* using data from personal digital devices’. (Onnela and Rauch, 2016).

6 Affective computing is the study and development of systems and devices that can recognize, interpret, process, and simulate human affects.

7 Neurogaming is a novel form of gaming that involves the use of brain-computer interfaces such as EEG helmets so that users can interact with the game without use of a traditional controller.

8 Neuromarketing is the study of the cerebral mechanisms likely to intervene in consumer behaviour.

9 Chile approved an amendment to its Constitution on 25 October 2021 that states: ‘El desarrollo científico y tecnológico estará al servicio de las personas y se llevará a cabo con respeto a la vida y a la integridad física y psíquica. La ley regulará los requisitos, condiciones y restricciones para su utilización en las personas, debiendo resguardar especialmente la actividad cerebral, así como la información proveniente de ella.’ Law 21383 SOLE Art. No. 1 and 2 DO 25.10.2021. ‘Scientific and technological development will be at the service of people and will be carried out with respect for life and physical and mental integrity. The law will regulate the requirements, conditions and restrictions for its use in people, and must especially protect brain activity, as well as the information from it.’ [Official translation from the website of the Biblioteca del Congreso de Chile].

10 France approved amendments to the Bioethics Law on 29 June 2021 that state: ‘*Brain imaging techniques may only be used for medical or scientific research purposes or as part of forensic expertise, excluding, in this context, functional brain imaging.*’ [Art 16-14, Civil Code]; that the use of data from brain imaging techniques for discrimination shall be punishable [Section 1 of Article 225-3, Criminal Code]; and that: ‘*Acts, processes, techniques, methods and equipment having the effect of modifying brain activity and presenting a serious danger or a suspicion of serious danger to human health may be prohibited by decree, after advice from the High Authority for Health. Any decision to lift the ban is taken in the same form.*’ [Article L.1151-4., Public Health Code].

OECD Recommendation on Responsible Innovation in Neurotechnology on 11 December 2019, aiming to guide governments and innovators in anticipating and addressing the ethical, legal and social challenges raised by novel neurotechnologies while promoting innovation in the field (OECD, 2019). At present these remain non-binding principles.

13. As these technologies can be used to improve the cognitive, sensory and motor capacities of some patients with neurological disorders, this opens doors for similar technologies to be used by neurologically healthy individuals for enhancement purposes. Human enhancement refers to a very broad range of techniques and approaches aimed at augmenting body or cognitive functions, that result in potentially improved characteristics and capabilities, sometimes beyond the existing human range. Augmentation technology should not only enhance the well-being and quality of life of an individual but also have positive effects on the community and society.
14. Neurotechnology was developed and used for health-related purposes, but it is increasingly applied in contexts outside the healthcare area. For instance, industry is incorporating neuroscience into the design of marketing tools, while the fields of teaching, gaming, and entertainment have also seen a growing interest in using neurotechnology to influence the brain in many ways. In these fields, specific attention must be given to children and adolescents, due to the particularly plastic state of the developing human brain.
15. Neurotechnology sits at the convergence point of neuroscience, engineering, data science, information and communication technology and artificial intelligence. Brain-related measurements can be combined with other digitally available information such as online searches, social media, self-tracked data and geolocation – sometimes referred to as ‘digital exhaust’. Advances in big data analytics and machine learning might enable a greater inferential capacity to identify patterns and predict outcomes based on the combination of different data sources (see *Report of the IBC on Consent* (UNESCO, 2008) and *Report of the IBC on Big Data and Health* (UNESCO, 2017a)).
16. The Universal Declaration on Bioethics and Human Rights (UNESCO, 2005) offers a general framework for analysing the legal and ethical aspects and implications of neurotechnology, especially Articles 2 (Aims); 3 (Human dignity and human rights); 4 (Benefit and harm); 5 (Autonomy and individual responsibility); 6 (Consent); 8 (Respect for human vulnerability and personal integrity); 9 (Privacy and confidentiality); 10 (Equality, justice and equity); 11 (Non-discrimination and non-stigmatization) and 13 (Solidarity and cooperation).
17. This report will investigate the intersection between neurotechnology, ethics and human rights, and consider the adaptive interpretation of human rights in light of the application of emerging technologies to human brain activities. More precisely, the scope of the report will embrace the numerous ethical and legal issues raised by ‘reading and/or writing’ the brain’s activity, and ask whether the questions raised are so important and so novel that we need a new set of neuro-specific human rights such as the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity; or whether those rights challenged by neurotechnology are already enshrined in existing human rights, but need more explicit protection through

precisely worded guarantees. For the purpose of this report, neurorights are defined as human rights-based *'ethical, legal, social, or natural principles of freedom or entitlement related to a person's cerebral and mental domain; that is, the fundamental normative rules for the protection and preservation of the human brain and mind.'* (Ienca, 2021b).



SHORT OVERVIEW OF EXISTING NEUROTECHNOLOGY



II.1. Neuroimaging

- 18.** Neuroimaging or brain imaging are techniques used to either directly or indirectly access the structure and function (reflected by electrical activity, oxygen and/or energy consumption, neurotransmitter release, etc.) of the central nervous system. These techniques are said to be 'non-invasive' if they do not need to open the skull to directly access the brain. They are otherwise said to be 'invasive'. We can cite here a few of the most common non-invasive techniques used today. They differ in terms of their spatial and temporal resolution. The most popular and accessible neuroimaging technique is electroencephalography (EEG), a method of brain exploration that measures the electrical activity of the brain using electrodes placed over the surface of the scalp. High density EEG (hdEEG) combines the superior temporal resolution of EEG recordings with increased spatial resolution. Computed tomography scanning uses computer-processed combinations of many X-ray measurements taken from different angles to produce cross-sectional images (virtual 'slices') of the brain. Magnetic resonance imaging (MRI) produces pictures of the anatomy of the brain using strong magnetic fields. Magnetoencephalography (MEG) is used for mapping brain activity by recording small magnetic fields produced by the electrical activity of the brain. Positron emission tomography (PET) is an imaging technique that uses radioactive substances injected intravenously to visualize and measure the metabolism of given brain regions. Cranial ultrasound is a technique for scanning the brain using high-frequency sound waves. It is used almost exclusively in babies because their fontanelle provides an 'acoustic window'. Functional near-infrared spectroscopy (fNIRS) is capable of visualizing changes both in oxy- and deoxyhaemoglobin concentration and is a rapidly developing non-invasive technique to evaluate changes in cerebral blood flow to given regions of the cerebral cortex. In particular, people wearing (mobile) fNIRS can move around in a relatively unconstrained way due to its robustness to movement artefacts, allowing their brain activity to be recorded in real life conditions. In this regard it is nothing like MRI, MEG, PET or EEG.
- 19.** Functional magnetic resonance imaging (fMRI) is a non-invasive method for studying the functional anatomy of the human brain. fMRI raises major ethical questions throughout the research process: 'from the conceptualization of experiments through their design, conduct, and analysis, to the interpretation and dissemination of results, and the possible implications and applications of research - informed consent - the investigation of incidental findings, the potential impact of neurological conditions on cognition and selfhood; also how brain images should be communicated: fMRI scans are highly processed representations of an indirect measure of neural activity, but are often described as if they are direct snapshots of the mind in action' (Garnett et al., 2011).

II.2. Neurodevices

20. Neurotechnology and neurodevices can replace parts of the body (e.g., robotic prostheses), and stimulate or inhibit functions of the brain (e.g., implanted deep brain stimulators), in order to improve people's health and well-being. Deep brain stimulation (DBS) involves implanting electrodes within certain areas of the brain. These electrodes produce electrical impulses that regulate abnormal impulses or affect certain cells and chemicals within the brain. The amount of stimulation in deep brain stimulation is controlled by a pacemaker-like device placed under the skin in the upper chest. A wire that travels under the skin connects this device to the electrodes in the brain. The fine tuning of the pacemaker is done in the hospital, and its activation remains under the control of the patient. Work-in-progress evaluates the integration of algorithms to adapt the stimulation to patient activity, and/or remote access through wireless devices.
21. Deep brain stimulation is approved to treat a number of conditions, such as Parkinson's disease, essential tremor, dystonia, epilepsy and obsessive-compulsive disorder. Deep brain stimulation is also being studied as a potential treatment for major depression, traumatic brain injury, stroke recovery, addiction, chronic pain, cluster headache, dementia, Tourette syndrome, Huntington's disease and multiple sclerosis.
22. The possible side effects of DBS are frequently underestimated. Complications of DBS fall into three categories: surgery complications, hardware (device and wires) complications, and stimulation-related complications. Manic psychosis, hypersexuality, pathological gambling and mood swings are associated with dopaminergic treatments of some advanced Parkinson disease, and there have been reports that these are made worse by DBS.
23. Transcranial direct current stimulation (tDCS) or Transcranial electrical stimulation (tES) involve devices delivering continuous currents supposedly to enhance concentration or relaxation. We observe the development of Do-it-yourself (DIY) neurotechnology with self-assembled devices for personal use by non-professionals to alter their brain functions.

II.3. Brain computer interface¹¹

- 24.** Brain Computer Interfaces (BCIs) are a type of neurotechnology that aims to translate brain processes that underlie thought and action into desired outcomes (e.g. enhancing mood in a depressed person or moving a prosthetic limb). This is made possible by collecting the data related to neural activity by sensors or electrodes placed in the brain, on the brain, or over the surface of the scalp, transforming them into a signal and then converting this signal into a mechanical or electrical action. BCIs are often directed at researching, mapping, assisting, augmenting, or repairing human cognitive or sensory-motor function (for example, in the case of a brain lesion resulting in hemiplegia, paraplegia or tetraplegia). They can be invasive, partially invasive or non-invasive. Invasive BCI requires surgery to implant electrodes within the grey matter of the brain, for directly relaying brain signals to device output, as in the case of treatments for non-congenital blindness.
- 25.** BCIs focusing on motor neuroprosthetics aim to either restore movement in individuals with paralysis or provide devices to assist them to communicate or physically interact with their environment, such as interfaces with computers or robot arms. Partially invasive BCI devices are implanted inside the skull but rest outside the brain, an example being Ecocorticography (EcoG) technology. Non-invasive EEG-based technologies and interfaces have been used for a much broader variety of applications. Neuroprosthetics is an area of neuroscience concerned with neural prostheses, using artificial devices to replace the function of impaired nervous systems and brain-related problems, or to replace the sensory organs themselves. The first neuroprosthetic device was the pacemaker.
- 26.** BCIs focusing on sensory prosthetics aim to restore the brain perception of sensory organs, such as eyes for sight or ears for hearing. While these devices are restoring sensory capabilities for millions, some people have raised the question of neurotypism in comparison with neurodiversity. Cochlear implants are an example of a device that has met with strong ethical challenges from the deaf community (Hyde and Power, 2006).
- 27.** Deep learning, partly modelled on biological processes occurring within the human brain, enables machines to recognize shapes and patterns. Brain Computer Interfaces use deep learning to decode brain activity, and some can help paralysed patients to regain speech or movement. The same kind of algorithms can be used to operate autonomous weapons systems (Drew, 2019). Deep learning can also be applied for medical tasks, with prominent examples being convolutional neural networks (ConvNets) on EEG signals (Schirrneister, 2017).

¹¹ A detailed description of BCIs is presented in Annex I to the present report.

II.4. Artificial Intelligence in neurosciences

28. Artificial Intelligence (AI) is a broad term that refers to the activity devoted to making machines 'intelligent', such as that required for computer vision or 'autonomous' robots. While there is no single agreed definition of AI, it is widely agreed that machines based on or incorporating AI are potentially capable of imitating or even exceeding some human cognitive capacities, including sensing, language interaction, reasoning and analysis, problem solving, and even creativity (Miraux, 2018). UNESCO's Recommendation on the Ethics of AI adopted by the 193 Member States of UNESCO in November 2021 approaches *'AI systems as systems which have the capacity to process data and information in a way that resembles intelligent behaviour, and typically includes aspects of reasoning, learning, perception, prediction, planning or control'*. To be able to perform such tasks, a device embedded with AI needs to be able to sense the environment and collect data dynamically, process it promptly and respond – based on its past 'experience', its pre-set principles for decision-making and its anticipation about the future. The ability to efficiently integrate dynamic data acquisition and machine-learning algorithms for prompt decision-making enables the creation of 'cognitive machines'. Cognitive machines are closely linked to neuroscience and neurotechnology.
29. The history of Artificial Intelligence is intertwined with the history of neuroscience itself. Pioneering scientists in AI (many of them originally from neuroscience) turned to the human brain for guidance for the development of intelligent machines (LeCun et al., 2015), and also borrowed most of the vocabulary from neurology and psychology, like artificial neural networks (although the neurons in question in AI are mathematical functions, not biological organisms).
30. This type of artificial intelligence does not rely on expert systems (a corpus of knowledge), but on large-scale statistical processing of information through an iterative learning process (Levy, 2018). With the ability to rapidly identify patterns in large, complex data sets, AI has seen promising results in the past decade, in part by emulating how the brain performs certain computations. Contemporary cognitive science can benefit from the power of AI, both as a model for developing and testing ideas about how the brain performs computations, and as a tool for processing the complex data sets that researchers are producing (Savage, 2019).
31. The convergence of AI, microsystems engineering and big data methods makes intelligent neurotechnological systems and AI-based algorithms for computational neuroscience one of the fastest growing fields of neuromedical research and innovation. These developments offer new possibilities for improving the understanding of brain disorders, identifying new biomarkers, building intelligent decision-support systems and many other

beneficial applications, but they also create important ethical, legal, philosophical, social and political challenges.

32. AI algorithms in clinical neuroscience research are used for predictive and diagnostic purposes, i.e. machine learning algorithms to detect early signs of Alzheimer's disease and mental disabilities from patterns of activity or structural anomalies in brain scans. There are many related ethical issues: automatic diagnoses changing the model of patient-doctor relationships, algorithm discrimination, incidental findings and privacy concerns, transparency and bias, among others.



NEUROTECHNOLOGY AND ETHICS



III.1. Neurotechnology and ethical principles

- 33.** 'Neuroethics'¹² (Figueroa, 2016; Dubljević, 2017) deals with the issues and study of ethical questions that emerge from scientific discoveries and technological applications in or on the brain. Neuroethics includes, on the one hand, the ethics of neuroscience, which is a moral framework for guiding research in the field of neuroscience and the technological application of its results in humans, and on the other hand the neuroscience of ethics, which aims to investigate the neurological basis of morality. In the framework of this report, the focus will be on the ethics of neuroscience, which is the main concern (though it has implicit consequences for the neuroscience of ethics).
- 34.** Currently, the use of neurotechnologies and their implications for the brain involve a high level of uncertainty about benefits and risks. Neurotechnologies have the potential to affect bioethics, both in theory and in practice, and require consideration of philosophical and ethical concepts: human dignity, personal identity, autonomy, mental privacy, accessibility and social justice. They also raise questions about accessibility, which is a common ethical concern with new technologies (in terms of justice and equity). Issues will be different depending on whether neurotechnology is developed in the health sector or beyond (including gaming, marketing, education, etc.). Specific problems emerge in the contexts of therapy and enhancement use.
- 35.** Any assessment of ethical issues raised by the use of neurotechnology should consider the context of their application. For example, a brain implant will not raise the same questions depending on the level of uncertainty both doctor and patient may accept if the possible benefits are important, and on whether it is being used to treat neurological disease such as Parkinson's disease or to treat a mental disability. However, in this latter case a lack of discussion has been reported concerning core ethical issues (informed consent, risk, safety, and incidental findings) associated with either the conduct or results of MRI research on mental disabilities (Anderson et al., 2012).
- 36.** The use of AI in combination with neurotechnologies raises issues of bias, discrimination and privacy. Brain information is probably the most intimate and private of all information. Digitally stored neural data could be stolen by hackers or used inappropriately by companies to whom users grant access (Drew, 2019).

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The term 'Neuroethics' is attributed to William Safire in the early 2000s (Safire, 2002).

III.1.1. Cerebral/mental integrity¹³ and human dignity

37. Given the growing neurotechnological possibilities for modifying the brain, and consequently the mind, including in an invasive and pervasive way, it is necessary to consider the integrity of the brain and mind in the framework of the integrity of the human body
38. Ienca and Andorno (2017) recognize 'mental integrity' as a value, faced with the neurotechnological possibility of provoking 'direct harm' caused by 'the unauthorized alteration of a person's neural computation'. In this perspective 'harm' is the violation of integrity, and 'benefit' is the preservation of integrity.
39. As mentioned in Article 1 of the Universal Declaration of Human Rights (UDHR): 'All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience [...].' In this perspective, the integrity of the body, and the brain/mind as part of the body, should be recognized, respected and protected from arbitrary alteration, modification or manipulation, which violates it and causes harm to the subject (who becomes an object). This is also recognized by Article 3 of the Charter of Fundamental Rights of the European Union: '1. Everyone has the right to respect for his or her physical and mental integrity.'
40. Human dignity is the fundamental value enshrined in human rights doctrine and in the Universal Declaration of Bioethics and Human Rights of UNESCO. However, because of philosophical pluralism, the concept of dignity has different meanings with differing ethical implications. At least three meanings should be mentioned in the context of the advancement of neurosciences and neurotechnology: ontological dignity, the very being and nature of every human being with the permanent possibility to increase or decrease their own natural/intrinsic capacities; transcendental dignity (Kant), whereby each person has a specific value because of the possibility of autonomy, of being an end in themselves; and existential dignity, whereby everyone has to construct themselves by each and every act in their life – to do one's best to decide one's life through every action. This might be easier for some people than others, but all individuals possess the same dignity defined as the will to construct one's life by oneself. Furthermore, on a libertarian view, dignity depends on an individual's ability or lack of ability to exercise their freedom.
41. The IBC recognises the pluralistic debate on human dignity but emphasizes that the recognition of the dignity of every human being is linked with human rights, and includes recognition of the integrity of the body and equality. In this sense the integrity of the brain/mind must be respected, considering any form of neurotechnological alteration, modification or manipulation as a violation of human dignity. Neurotechnology may also be a powerful tool to restore human dignity through rehabilitation and returning to autonomy.

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Mental Integrity is an individual's mastery of his or her mental states and his or her brain data so that, without his or her consent, no one can read, spread, or alter such states and data in order to condition the individual in any way. (Lavazza, 2018, ref. 26).

III.1.2. Personal identity and psychological continuity

- 42.** In the history of thought, two main approaches to the concept of personal identity have been developed. The first is a concept of personal identity based on substance: at different times, a person is identical to another because both are made of one and the same substance. The second approach is a relational and temporal concept of personal identity: at different times, a person is identical to another because relationships exist between them. As we will see, the determination of these relationships varies according to philosophical concepts.
- 43.** Contemporary reflection on personal identity has mostly been built upon the thinking of John Locke (Locke, 1674), and whether to validate or criticize Locke's original ideas. As a seventeenth century philosopher, Locke distinguished biological identity (uninterrupted participation in the same life dynamic) from personal identity conceived in a relational way. Personal identity is based on self-reflective consciousness.¹⁴ The criticisms of this concept can be broken down into five major approaches.
- 44.** The first approach is the psychological approach (Butler, 1736; Reid, 1785; Shoemaker, 1996) according to which psychological continuity exists between any two given moments of a person's existence, made up of an overlap of psychological connections such as memory, desires, likeness of character, etc. For the second, biological, approach (Wiggins, 1980), personal identity is based on a biological substrate, and the identity of the person remains unchanged whether or not he had such a desire, such a memory, etc. The third is the narrative approach, which suggests that it is necessary for a person to integrate into the story of their life the events that affect them to give them coherence and intelligibility. The fourth approach, based on a social approach to identity (Nelson and Lindemann, 2001; Schechtman, 1996), highlights the contribution of third parties in the construction of a personal identity and in its recognition over time. The fifth approach is the reductionist approach (Parfit, 1984) that affirms that the facts about personal identity are facts about the brain, the body, or the interconnection of physical and mental events.
- 45.** The psychological approach to personal identity requires any neurotechnological modification to preserve the possibility of establishing a link with mental content (memories, etc.) and psychological characteristics from the past. The biological approach assesses the extent to which a neurotechnological intervention affects the biological substratum of personal identity. The narrative approach to identity takes as a criterion the fact that a neurotechnological intervention is not a substitute. The social approach relies on the perception by a third party of the possible modification of identity following a neurotechnological intervention. Finally, the reductionist approach judges a modification of identity following a neurotechnological intervention by establishing a link between the new cerebral characteristics and mental events.

¹⁴ A and B are identical persons in time if they are connected by consciousness, that is to say if B remembers the thoughts and experiences of A. From the ethical point of view, it means that A will be held responsible for the actions of B if A remembers these actions.

46. Continuity and distinctiveness of the self are bodily and ethically embedded. The way in which the self is bodily embedded is twofold: on the one hand, being a self presupposes 'being a body'; on the other hand, being a self presupposes 'having a body' (Plessner, 1927). Authenticity can mean that a person is fully themselves when he or she acts according to their desires and preferences, or that if a person acts independently, responsibly, and sincerely, they are acting authentically.
47. To understand whether neurotechnology poses a threat, and if so what type of threat, to the personal identity and authenticity of the self, we consider two examples: first, that of memory modification techniques, then that of deep brain stimulation.
48. Memory modification techniques (MMT) frequently use pharmacological means and may eventually (also) rely on implanting chips in the brain. These approaches make it possible to improve memory (memory enhancement), as in the case of cognitive improvement, for example. They also allow individuals to choose to alter the content of memory (memory editing). In the latter case, MMT can completely erase a memory, induce amnesia, or reduce the emotional impact of a painful memory and reduce the risk of post-traumatic stress disorder. Deleting a memory reconstructs the memory of past events and therefore personal identity. The reconstruction of this identity, in itself, is not at fault; it is what happens when past experiences are integrated so as to repeat them or avoid them in the future. The problem arises when this choice of memory content is imposed by a third party, and the person can no longer relate to who they were before. Their perception of what they have experienced in the past is distorted and their responsibility may appear different, which affects personal identity and authenticity.
49. Deep Brain Stimulation (DBS) can pose a threat to an individual's mind-to-body unity as their authentic self. Unquestionably, while the body regains appreciable autonomy in its movements, the mind can be disoriented by the active presence of the technical device. The individual experiences a feeling of alienation that bodily improvement cannot eliminate. The control exerted by the DBS on certain parts of the body is experienced as a form of subjugation of the person to the technical device. Added to this is the possibility that the device can be controlled remotely by a clinician, perhaps without the patient's knowledge. Note that this possibility is not specific to DBS but to any device implanted or linked in one way or another to a human being.
50. Depending on the type of pathology, the perception of the impact of DBS on personal identity varies. In Parkinson's disease, it aims to reduce motor symptoms. In the context of obsessive-compulsive disorders, which appear earlier in life, it is the behaviour of the person, including their way of thinking and feeling, that is targeted. But even in this case, it is precise changes in behaviour rather than a radical change in the person that patients seem to suggest. In addition, depending on the type of pathology and the duration of the patient's experience of this pathology, some people have integrated this pathology into their personal identity. They feel more authentically themselves with the pathology than without it. This indicates that there is no universally experienced correlation between the notions of health and authenticity, disease and alienation.

III.1.2.1. Neurotechnology and the developing brain: personal identity of children and adolescents

- 51.** All the emerging issues related to personal identity and neurotechnologies raise the ethical need for precaution in the face of the risks and uncertainties. It is becoming increasingly clear from studies of development of the brain and its relationship to other biological systems in the prenatal, perinatal, early childhood and adolescent periods that historic debates about the ascendancy of genetics (nature) or environment (nurture) have been superseded by a still-evolving understanding of the complex interaction between nature and nurture that shapes the growing child: emotionally, socially and behaviourally.
- 52.** The complex interaction between genetics and life experience shapes the development of neurobiological systems, particularly in the prenatal/early childhood and adolescent periods. Early experience impacts the structure and function of the developing brain. Epidemiological evidence reveals an association of experiences in the prenatal and early childhood period with later health and well-being (Black et al., 2017). The brain develops rapidly during this period, a time during which experiences shape the developing brain, with implications for health, learning and behaviour throughout the person's lifespan.
- 53.** Neurotechnology has the potential to transform children's and adolescents' plastic, still developing brains in myriad ways that will shape their future identity with long-lasting, if not permanent, effects. Embedding neurodevices and BCIs while an individual is still undergoing significant neurodevelopment (thought to continue until at least 25 years of age) makes it difficult to distinguish which character traits and behaviour can be attributed to the neurodevice versus the 'normal' maturation of the brain. This is a cross-cutting issue that needs to be kept in mind as we discuss other aspects of the ethical impacts of neurotechnology.

III.1.3. Autonomy

- 54.** We understand autonomy as the ability to define our personal goals and the freedom to decide accordingly, implying intentionality, awareness and the absence of influences that determine our actions. We consider that autonomous actions have to be analysed according to the following requirements: a) intentionality; b) awareness and c) absence of external influences intended to control and determine one's action (Beauchamp and Childress, 2001). Autonomy is the capacity that a person has to exercise their own individual freedom, which is conferred by the mere fact of birth.
- 55.** The increasing neurotechnological possibilities of cognitive monitoring/surveillance and influence in the form of manipulation or alteration of cognitive functions, brain/mental decoding, reading and (possibly) writing represent possible interferences with cognitive processes, and above all with free and competent decisions of the individual. To lose one's autonomy means to lose the capacity for freedom but not the right to freedom. For this

reason, the protection society grants to the effectiveness of the right to freedom must take into account the degree of vulnerability of an individual person.

56. The human being is a social being in a situation of continuous external influences. Autonomy refers specifically to this capacity for distancing and personal choice, in a context where influences are multiple. Through language in particular, the human being is able to distance themselves from these influences and use the leeway left to them by neurological constraints to articulate their behaviour around a system of meanings they construct in a personal way, but in relation to their cultural and societal context. (Habermas 2008, MacWhinney, 2015). The debate, both experimental and philosophical, about the existence/nonexistence of free will (starting from Libet's experiment¹⁵) is considered not relevant for the bioethical discussion in this context.
57. Our current increasing knowledge of the human brain can lead us to question whether human beings can in effect take autonomous decisions. If neurotechnology can measure and change (improve, treat, obstruct, enable or enhance) our capacity, the degree of autonomy of that person after the intervention should be questioned. Do the decisions taken before the intervention remain after any changes? If so, it is mandatory to reformulate the previously expressed declarations of will. Use of DBS offers examples of benefits (increased autonomy) as well as risks (forgetfulness and word-finding problems, depression or suicide; Zygmunt and Domitrz, 2020).
58. In the context of neurotechnologies, we have to consider two different perspectives. The first is autonomy to consent to the use of neurotechnology on the subject's body – as a participant in a research study, as a patient benefiting from a therapeutic application, or as a consumer (of a medical or non-medical grade neurotechnology device). The second is focused on the acquisition, data handling, use and sharing of neural data for different ends as developed in the legal chapter.
59. The relevant ethical concerns here relate to the role of therapeutic neurotechnologies in restoring – or possibly disrupting – an individual's capacity to exercise their autonomy and identity as a result of an intervention in the brain or manipulation of neural activity.
60. Brain damage or intervention may disrupt the identity which results from each individual's specific personal history. Neurotechnology used for rehabilitation can help to restore a person's capacities and their autonomy.
61. DBS may interfere with the natural process of decision-making, raising questions about the person's self-governing capacity, especially when DBS devices are controlled by closed-loop systems that increasingly use AI software to autonomously adapt their operation.

15 Libet invited participants to move their right wrist and to report the precise moment when they decided to do so, thanks to a big clock they had in front of them. In this way, it was possible to estimate the time of awareness with respect to the beginning of the movement. During the execution of the task, brain electrical activity was recorded. The 'readiness potential' originated from a brain area involved in motor preparation, and was visible in the EEG signal as a wave that starts before any voluntary movement and before the time of awareness of the decision reported, while being absent or reduced before involuntary and automatic movements. It was proposed that the voluntary movement was initiated unconsciously (Libet et al., 1993).

III.1.3.1. Autonomy and informed consent

62. 'Consent is one of the basic principles of bioethics because it is closely linked to the principle of autonomy and because it reflects affirmation of human rights and human dignity which are the core values of democratic societies' (UNESCO, 2008).
63. Article 6 of the Universal Declaration on Bioethics and Human Rights (UDBHR) provides that any preventive, diagnostic and therapeutic medical intervention as well as scientific research should only be carried out 'with the prior, free, express and informed consent of the person concerned' (UNESCO, 2005). The Nuremberg Code underscores consent and is at the origin of the concept that participation in research is a voluntary activity. The Declaration of Helsinki also enshrines consent as a main guarantee (WMA, 2013).
64. As an expression of autonomy, informed consent in neurotechnology is transversal to different situations such as the possible changes to decision-making competence. Specific privacy issues have to be analysed for direct-to-consumer products, taking into account that, on the one hand, the use of a neurodevice may have both direct and indirect influence on one's privacy and, on the other, that consent to use of personal data for broader purposes may have other impacts on one's privacy.
65. The use of neurotechnologies may interfere with the individual's cognitive process of perception and understanding. In other words, the use of neurotechnologies might call into question whether human beings can actually take autonomous decisions. This could be an issue after a rehabilitation or enhancement of the brain. On the other hand, neurotechnologies may facilitate new methods for evaluating autonomy (e.g. by measuring brain activity).
66. Ethical dilemmas in surrogate decision-making are acute when it comes to neurodevices, given all the dimensions that must be considered and the dynamic evolution of brain functions and capacity (in relation to the device). Respect for the autonomy of children requires special attention in order to preserve their future capacity to make autonomous decisions, once they acquire the maturity and the legal right to consent on their own. Although it is expected that parents act in their children's best interest, requesting information of a predictive nature or making decisions on behalf of a child whose potential health condition will most likely occur in adulthood could be inconsistent with respect for their autonomy.
67. Concerning Deep Brain Stimulation, some neuroscientists acknowledge that 'currently, consent forms typically focus only on the physical risks of (neuro)surgery, rather than the possible effects of a device on mood, personality or sense of self' (Yuste et al., 2017). Moreover, it is understood that 'current trends in research study procedures often result in extremely long and legalistic informed consent forms, which ironically do little to protect the individual. Providing people with an ability to ask questions and understand in depth what they are signing up for becomes increasingly more important as interventions become increasingly more potent' (Jarchum, 2019).

68. An individual must receive understandable, relevant, structured and individually tailored information that makes it possible for that individual to make a decision on whether or not to accept medical intervention or to participate in scientific research (UNESCO, 2008). It has also been established that one of the most important aspects of information to be provided is information about possible risks and benefits related to a proposed medical or scientific intervention; this is a key component in obtaining consent. Medical or scientific interventions may involve a complex ratio of benefits and risks and it is the duty of healthcare professionals to convey to a patient or research participant this information in intelligible language (UNESCO, 2008). For neurotechnology, on many occasions the risks and benefits are still uncertain, therefore doubts about the validity of informed consent may arise because of the lack of required information.
69. In the context of bioethics, some argue that, in view of the corresponding principle of non-maleficence there is an obligation to avoid harm in those new treatments where we have the knowledge about the harm they may cause, the long-term effects on the brain and on the person's experience, the changes that may occur and the uncertainty of the consequences. 'The obligation to avoid harm requires an ongoing commitment to develop a robust body of evidence, attention to the needs and vulnerabilities of particular individuals, and a willingness to reflect upon and review clinical practices and the development trajectories of these technologies' (Nuffield Council of Bioethics, 2013).
70. In such circumstances, some recommend what they call the application of the 'principle of caution', referring to a 'less restrictive standard of behaviour, one which is tempered by the recognition that some risks, and some uncertainty about risks, may be tolerated where technologies could make a significant contribution both to individual patients and to the public good' (Nuffield Council of Bioethics, 2013).
71. Using AI tools also introduces ethical issues of which regulators have little experience. Machine-learning software learns to analyse data by generating algorithms that cannot be predicted and that are difficult, or impossible, to explain. This introduces an unknown and sometimes unaccountable process between a person's thoughts and the technology that is acting on their behalf (Drew, 2019).

III.1.4. Mental Privacy¹⁶

72. As has been explained in our previous *Report of the IBC on Big Data and Health* (UNESCO, 2017a), the right to privacy is closely linked to the right to freedom with its diverse legal and ethical aspects like freedom of speech, association, location, movement and space, beliefs, thoughts and feelings, and behaviour. Against this background, the IBC uses the

¹⁶ Mental privacy refers to the explicit protection of individuals against the unconsented intrusion by third parties into their mental information (be it inferred from their neural data or from proxy data indicative of neurological, cognitive, and/or affective information) as well as against the unauthorized collection of those data (Ienca and Andorno, 2017).

term privacy to mean the right to respect for an individual's wish to reserve certain areas of their private life for themselves or specific family members or others.

- 73.** Neurotechnology may transmit brain data and digital data related to the brain activity of its users. Implanted neurodevices such as those used in DBS, and even non-implanted devices might also record patients' brain activity. Information collected and processed from neurodevices can be obtained and used to identify someone, or reveal their brain activity, particularly where this indicates a stigmatizing neurological or mental health condition or could otherwise be used for discriminatory purposes.
- 74.** 'Mind reading', especially in relation to data unexpectedly found or detected, based on the neuroimaging of psychological states unknown to the individual and which were not considered among the range of possibilities or risks of detection, can have personal implications and give rise to very complex social issues. However, such data may be obtained without the knowledge (thus without the consent) of the individual, or without their even being aware that such information is being obtained.
- 75.** 'The new possibilities of monitoring and manipulating the human mind through neuroimaging open the possibility of transgressing the right to privacy of individuals, accessing not only their behaviors, but also their thoughts, which can have consequences of great caliber' (Gracia and Jambrina, 2019). Brain recordings can be predictive of a neurological disease (for example early signatures of dementia that can be inferred from neuroimaging biomarkers).
- 76.** Some of those consequences have already been raised by genetic research, mainly those regarding the access to such information by third parties (employers, insurance companies) (UNESCO, 2015b). The same may apply to neural data.
- 77.** The question therefore is: may neural data be considered, and thus treated, as health or personal data? And if yes, what makes neural data different from other data? These are data from a person's brain. It must be remembered that the mind is generated by the brain. These are the only data that reveal a person's mental processes. If the assumption is that 'I am defined by my brain', then neural data may be considered as the origin of the self and require special definition and protection.

III.1.5. Accessibility and social justice

- 78.** The problems posed by brain disorders might be seen to present more significant challenges in less developed regions, where they may carry significant stigma and where public health infrastructure and access to treatments for such disorders are very limited. It is therefore desirable that research scientists, technologists, funders and industry partners should work together to develop ways of making access to novel neurotechnology a more realistic possibility for those who need it.

79. Since there is a higher incidence of neurological and mental disorders in populations living in poverty, it is foreseeable that there may be increasing demand for the medical applications of neurotechnology among these populations. In such circumstances strong regulations will be needed both to ensure that potential uses of neurotechnology meet the highest bioengineering and medical standards and to prevent deceptive advertising and misuse. These regulations should be developed embracing the principles of responsible innovation, such as ensuring public accountability, inclusiveness, representativeness, enforceability and active participation during the process of both design and application (Daniels, 2008).
80. In contexts of deep social inequality, neurotechnologies might potentially offer a way of compensating those patients suffering from neurological or mental disorders that could have been avoided if they had not had to live in conditions of poverty. Conversely, limitations on access to those technologies would constitute a source of greater inequality. In order to strengthen the former and reduce the possibilities of the latter, it is imperative that access to potentially scarce neurotech-therapies (potentially expensive for low-income countries) be regulated according to fair distributive justice principles such as non-discrimination, highest potential medical benefit, social equity and transparency (WHO, 2016). Governments should begin to design and implement public policies focused on reducing brain health inequalities in the population – i.e. by ensuring high quality nutrition in early childhood as well as healthy and stimulating cognitive and emotional environments (Daniels, 2007; WHO, 2016).
81. The principle of non-discrimination with specific consideration for the particularly vulnerable is expressed in many previous reports of the IBC including its *Report on the Principle of Individual Responsibility as related to Health* (UNESCO, 2019, pp. 38 and 42), *Report on Big Data and Health* (UNESCO, 2017a, pp. 33), *Report on Social Responsibility and Health* (UNESCO, 2011, pp. 8-9, 40, 45 and 63), *Report on the Bioethical Response to the Situation of Refugees* (UNESCO, 2017b, pp. 61 and 70), *Report on the Principle of Non-discrimination and Non-stigmatization* (UNESCO, 2014, pp. 27 and 29), *Report on the Principle of the Sharing of Benefits* (UNESCO, 2015a, pp. 43, 44 and 112), and *Report on Updating Its Reflection on the Human Genome and Human Rights* (UNESCO, 2015b, pp. 3, 19 and 44).
82. Ensuring equitable access to neurotechnologies requires, among other things, effective governance of data-sharing practices. Cultural differences and a diversity of governance systems, in particular, can complicate data sharing (Garden et al., 2019, p.7). These challenges can be addressed through responsible translation of brain research from laboratory to commercialization.

III.2. Enhancement purpose

- 83.** Neurodevices have the potential to become integral parts of the lives of the people who use them and can cause changes in their personal and social identity. Neurodevices that can change a person's mood (e.g. DBS in major depressions) call into question the authenticity and adequacy of the user's emotions in a real-life context and can create problems in terms of how the user relates to other people at different times (i.e. with the device activated vs. deactivated). Neurodevices incorporate data on the abnormal state to be corrected as well as data on the state of normality to be obtained, thus calling into question the concept of normality in the functioning of the human brain or body. Normality should be understood here as the functioning observed in healthy brains. Defining the concept of normality is also essential in order to distinguish the pre-existing condition from the neuro-enhancement which can be obtained by using neurotechnology. In the future, sensorimotor normality could very likely be different in elite athletes and other performers (musicians, dancers, etc.), and neurodevices could provide all manner of performance enhancements in the sensorimotor domain. The IBC recognizes that the challenge of defining normal brain functioning will vary across different domains and dimensions of the mind, such as sensorimotor performance, moral reasoning, face perception, etc.
- 84.** Neuro-cognitive enhancement¹⁷ refers to interventions designed to improve mental and emotional performance considered as 'normal', using recent advances in neuroscience and neurotechnology involving the brain tissue itself, as well as the neurophysiological mechanisms that govern cognitive functions, including psychotropic drugs affecting mental processes, neuroimaging technologies to assess or alter brain function via neurofeedback, neurostimulation technologies to transiently alter brain function, such as transcranial magnetic stimulation or transcranial direct current stimulation applied over the cortex, or surgically embedding brain implants and employing a brain-computer interface. Neurocognitive enhancement encompasses diverse methods of intervention, more or less invasive with regard to the body, with short- and long-term consequences. Despite their differences they share common goals of intervention, which can be identified as enhancing human capabilities, 'beyond' therapy.
- 85.** Moral neuro-enhancement (Persson and Savulescu, 2012) refers to the use of drugs and technologies on healthy subjects to try to improve moral dispositions and capacities, such

¹⁷ There are many reports and opinions of committees for bioethics on this topic. See U.S. President's Council on Bioethics. 2003. *Beyond Therapy: Biotechnology and the Pursuit of Human Improvement*; Health Council of the Netherlands. 2003. *Human enhancement*; The Danish Council of Ethics. 2011. *Medical enhancement*; Commission nationale d'éthique dans le domaine de la médecine humaine (NEK-CNE). 2011. *L'amélioration' de l'humain par des substances pharmacologiques*; National French Consultative Ethics Committee for Health and Life Sciences. 2013. *Recours aux techniques biomédicales en vue de 'neuro-amélioration' chez la personne non malade: enjeux éthiques*, Opinion No.. 122; Italian National Bioethics Committee. 2014. *Neuroscience and pharmacological cognitive enhancement: bioethical aspects*.

as the sense of justice, sympathy, empathy, altruism, cooperation, attenuating or removing aggressiveness, conflicts, prejudices and hatred. This kind of enhancement could be carried out by means of drugs, neuro-technologies that activate cerebral areas (like the amygdala) by means of deep brain stimulation or brain implants correlated to emotive responsiveness, the alteration of moral perception or the control of violent behaviour, a requisite of moral conduct (the 'moral brain'). Little, if any, scientific literature supports such possibilities in real life as yet.

86. In the non-medical field (non-therapy derived) there are already games on the market using BCI technology that relies upon non-invasive brain imaging techniques such as electroencephalography (EEG) and functional near infrared spectroscopy (fNIRS). There is research activity to develop commercial games that are BCI-controlled. These neurotechnology-based approaches are used for recreational purposes. A large number of people use these applications, with the lack of any clear evidence on benefits/risks. Despite the risks associated with some of these unnecessary applications, they are used without medical monitoring (in private settings).
87. In military settings (Italian National Committee for Bioethics, 2013), novel neurotechnology potentially has applications in treating physical and psychiatric injuries, enhancing fighters' physical, cognitive, and emotional capacities, or permitting neural remote control of weapons. Military applications of novel neurotechnology raise particular challenges because of the vulnerability of military personnel in a hierarchical setting.
88. Augmentation technology may have positive effects on individuals with a low range of abilities, when introduced for therapeutic purposes in order to improve their capacities. In this sense it may have a positive effect for community and society. The blurring between enhancement and therapy comes from the subjectivist view of health, considered as a state of complete physical, mental and social well-being. In this perspective, enhancement is equated with therapy, insofar as a reduced capacity may be subjectively, socially and culturally perceived as a source of discomfort or an illness. The subjective perception of 'normality' plays a role in this blurring. In the case of cochlear implants for deaf children, the particular concept of 'normality' that underlies the promotion of such implants for therapeutic purposes of has, in fact, been challenged by deaf communities that do not consider their condition as something that needs to be corrected or improved.
89. Arguments in favour of enhancement (Savulescu et al., 2011; Harris, 2010) start from the idea that enhancement and therapy are interchangeable, contiguous and equivalent, with improvement considered, consciously or unconsciously, as part of human development, individual or social opportunity, whether the enhancement is natural or artificial (pharmaceutical or technological). It is considered a 'short cut', a self-determined choice by a free individual, in a free market, on the libertarian view. From the utilitarian perspective, enhancement is considered a stage of evolution to be replaced by the 'deliberate choice' of the selection process, allowing the same result to be achieved rapidly and with much less effort. Although possible negative outcomes still remain unknown, to halt progress in this direction would imply hampering or preventing the possibility of accelerating human evolution. This theory of 'self-evolution' and 'enhancement evolution' would shorten the

time required for millions of years of evolutionary progress, allowing man and humanity to attain and realize their full potential, in order to balance the effects of what, in physical and social terms, is a natural lottery. This approach justifies a 'duty to enhance' as a 'duty of beneficence', which is not only individual but also collective.

90. The critical approach (Kass, 2002; Fukuyama, 2006; Sandel, 2007) to enhancement underlines the threats to dignity of attempting to overcome (i.e., not accepting) the limits of nature. The use of technologies for improvement purposes can cause serious harm, disproportionate compared to the expected benefits of the fulfilment of subjective desires. Excessively risky interventions in terms of the achievable benefits (deemed ineffective, costly and burdensome for patients), as well as irreversible and predictably inconclusive interventions, cannot be ethically or deontologically¹⁸ justified, even if requested by patients. On this view enhancement is a 'fraudulent misrepresentation' to the detriment of others. By contrast with enhancement, achievement encompasses the dimension of acquiring, in the sense of developing and realizing potential naturally, through an active effort and personal commitment that enable modification of one's own natural capacities. In this sense, enhancement is expressed in the hidden pressure exerted by society on individuals to adapt to standards of mental efficiency in studying, working, sports performance and society in general. This gives rise to an enhancement divide, a divide between the enhanced and unenhanced. It presents us with problems of equality, inevitably introducing differences which increase disparities and discrimination between rich and poor, advantaged and disadvantaged. The strong push towards improvement resurrects the ethical problem of eugenics, understood as the selection of the best, here on the basis of neurocognitive characteristics, which is to jeopardize 'the inherent and therefore equal dignity of all human beings and renew eugenics, disguised as the fulfilment of the wish for a better, improved life' (UNESCO, 2015b).
91. One especially vulnerable category is that of children. Special attention must be given to children because of their particular vulnerability, and the possible long-term effects (still not fully understood) of this type of nootropic on a brain still in development. There are also ethical concerns to be addressed concerning the use by teachers and parents of helmet electrode recordings to monitor children's brainwaves in order to assess awareness and attention. If these techniques contribute to improved pedagogical methods, they could be beneficial by contributing to the development of the child. However, if they are a new tool of surveillance and constraint, they appear to be contrary to the best interests of the child. Technology should be assessed to ensure the best interests of the child.
92. Paediatric enhancement is a rapidly developing area of concern, involving tools to influence children's cognition in ways that improve their capacities. These issues appear in a different light given new paths in technological development and changing demands and expectations regarding parenting.
93. In addition to children, other persons of concern are individuals with mental disabilities, persons who can easily be manipulated because of a specific weakness or dependence

18 Deontology is the duty enshrined in the professional code of the researcher.

(e.g. drug addicts), captive institutionalized populations (prisoners, pupils, adolescents in supervised education, young people in homes, members of the armed forces, refugees, etc.) (UNESCO, 1995).

94. The dual use of drugs and technologies (the fact that they may have clinical applications in therapeutic settings and may also be applied in non-medical contexts for enhancement purposes) makes their ethical justification particularly sensitive and troublesome. A total ban on research and use of technology may a priori hinder the development of a number of possible therapies; at the same time, the discovery of certain technologies may encourage their use for enhancement purposes. The dual-use argument, which was generally brought up by bioconservatives to emphasize risks, is now being used by bioprogressives to justify some development methods.
95. Novel neurotechnology has potential applications in military settings in treating physical and psychiatric injuries caused by combat, as well as non-therapeutic uses, such as using BCIs to enhance fighters' effectiveness. Novel neurotechnology also has potentially applications in enhancing fighters' physical, cognitive, and emotional capacities, or by permitting neural remote control of weapons. It is also plausible that BCIs or other neurostimulation approaches could be used for interrogation purposes. Military clinicians can play an important role in protecting the well-being of personnel with appropriate information. Military applications of novel neurotechnology raise particular challenges because of the vulnerability of military personnel in a hierarchical setting.
96. There has, to date, been no research study or proof of safety and efficacy of the use of pharmaceuticals or neurotechnology in off-label use in medical fields for enhancement purposes or for well-being (relaxation, sleep improvement, etc.). A number of small studies, most of them occasional with non-systematic analysis using neurotechnology, report improvements in participants' performance in a laboratory (for example memory or language skills, or in their mood). There is no statistically relevant sample, no repeated or repeatable test, and no validated proof. Great care is needed in extrapolating from small studies conducted under laboratory conditions to lasting real-world effects; the potential use of neurostimulation for neural enhancement is still far from proven. Not only have no trials been carried out on this, but it would also be extremely problematic from an ethical point of view to experiment with such interventions on healthy subjects, given the absolute uncertainty and the possible high risks associated with non-therapeutic and moreover implausible objectives. Obtaining informed consent is another particularly delicate aspect, and is an indispensable requirement of all legitimate research. The potential use of neurostimulation for neural enhancement is still far from proven. The discussion is more speculative than realistic. But applications are already applied or close to being applied both in the medical and non-medical fields.
97. There is also the risk, in a competitive society, of a sort of medicalization and pathologization (searching for drugs and technologies to improve performances), of not considering the social/environmental causes and of disease-mongering to market pharmaceuticals. The justification of proportionate risk – the level of risk considering the absence of a disease-

based need – is a particularly sensitive issue.¹⁹ These interventions are not necessary, but optional, selected by subjects experiencing non-disease conditions with the aim of feeling ‘better’. A profile emerges of the responsibility of health professionals, who must ensure the appropriateness of the prescription and therefore prevent ‘improper’ non-therapeutic use of these drugs.

98. Uses of non-invasive neurostimulation or BCIs either for ‘enhancement’ purposes or gaming do not generally pose serious health risks. However, the large number of people that use these applications and the lack of any clear associated health benefits mean that it is important to address several ethical concerns. In particular, to minimize the pursuit of unnecessary brain interventions, there is a need to ensure the originality and rigour of research investigating non-therapeutic uses in humans and also to disseminate existing evidence. There is a particular concern in children, in whom the effects of neurostimulation or BCIs on the developing brain are not well known. Observational research with children who are already using neurotechnology is needed to address this, and advice should also be issued to teachers and parents about the current evidence on the efficacy of neurofeedback as an educational enhancement tool.
99. Consideration should also be given to the fact that cognitive function can be improved in a more lasting manner through instruction, education and continuous training, through a rich social life, relationships, study, learning, the continuous stimulation of hobbies and interests, and by leading a healthy lifestyle (in terms of nutrition, physical activity, etc.). It is a path that clearly requires a lot of time, but is (perhaps) more respectful of the opportunities for growth and development of personal and relational identity.
100. The use of neurotechnology for enhancement raises several ethical concerns about freedom and justice.²⁰ Supporters of the concept of human enhancement claim that all those worries can be overcome by the advance and wider availability of technology, and that the limits of what it means to be human are a matter for debate.

19 Here the reference to risks in research ethics should be applied (CIOMS, 2016).

20 ‘The transition from ‘natural’ methods of improvement to others, such as the incorporation of new technologies to our bodies (...) has raised moral concerns regarding freedom, since there might be a hidden pressure to enhance, justice in the distribution of these technologies, the unfair advantages enhanced individuals would have in comparison to non-enhanced ones, and the meaning of human dignity, liberty and justice’ (Allhoff et al., 2011).

III.3. Neurotechnology and clinical ethics

101. Clinical ethics is a practical approach to making ethical decisions within a healthcare setting. It incorporates many of the ethical principles and rules fundamental to bioethics, such as respect for the autonomy of persons, beneficence and non-maleficence, confidentiality, informed consent, decision-making capacity, risk-benefit analysis, the best interest standard, the right to refuse treatment, withdrawing treatment, and procedural and distributive justice. Most of these principles and values are inseparably linked with the individual and their concept of self, their human rights, and the function of their brain.
102. Ethical issues of neurotechnology within the clinical setting are therefore concerned with illness or damage to the brain that can lead to serious disorders that affect memory, cognition, movement, or consciousness. With the brain having limited capacity to repair damaged tissue, the novel neurotechnology has the potential to address some of the disabling effects of brain damage by intervening in the functions of the brain itself. However, its processes and uncertainties may challenge some of the principles and values that are fundamental to clinical ethics.
103. Any tension between clinical need and scientific uncertainty requires ethical prudence within the clinical setting. Uncertainty exists regarding the benefits and risks of these technologies due to their newness as well as the lack of a comprehensive understanding of how the brain works. The 'special status' of the brain therefore provides both a reason to exercise beneficence as well as non-maleficence (to the greatest possible extent) by intervening when illness causes disorders of the brain.
104. Application of the principles involved in clinical ethics to neurotechnological developments therefore requires prudent intervention in disorders of the brain while strictly adhering to protecting personal privacy and the confidentiality of data, meticulous informed consent processes, and seeking to benefit others from the data obtained during the process of neuro-technological developments.
105. Even in the context of clinical settings, special consideration should be given to vulnerable human beings and neurodevices. Procedures that are irreversible (surgical lesions) or that have the capacity to produce imprints in children's brains with lasting effects on their development, self-identity, liberty and capacity require careful consideration and close monitoring. For instance, the decision to surgically implant a cochlear device should take into consideration the stage of development of the child (including the language development stage, neuromotor skills, etc.), but could also take into account other social considerations, in order to ultimately be 'beneficial' to a human being. Indeed, deafness is a condition with very different social perception and social construction, and is considered

by some groups of deaf people as a condition that does not need to be considered as a disease. Full consideration of issues relevant to neurodiversity will require further development, which is beyond the scope of the present report.

- 106.** As the clinical application of neurotechnologies may impact personal identity, autonomy and privacy, accessibility to these technologies should always be underscored by considerations of justice and equity. Further, neurotechnological innovations such as artificial intelligence and brain-computer interfaces must respect and preserve people's privacy, identity, agency, and equality.

III.4. Neurotechnology and research ethics

- 107.** Research in neurotechnology must comply with accepted ethical standards for research, mainly expressed in the Declaration of Helsinki, the 2016 International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) and other international health research regulatory bodies. All proposals to conduct research that involve human participants must first be submitted for a review of their scientific merit and ethical acceptability by an independent ethical review committee, which must give its approval in order for the research to proceed.
- 108.** Individuals as well as whole communities may be vulnerable to exploitation in research, and so the sponsors of research, researchers, and other relevant stakeholders must make every effort to ensure that the research is responsive to the health needs and priorities of the community or population in which it is to be carried out, and that any intervention, product developed, or knowledge generated will be made reasonably available for the benefit of that community or population.
- 109.** As the neurotechnological developments progress, ethical review of the process should also proceed hand-in-hand with the scientific development. Research outcomes such as the utility of 'brain data' should be subject to ethical considerations such as non-discrimination and privacy protection (for example, to prevent re-identification and unauthorized re-use), and ensuring benefit also accrues to those who participated in the research. Researchers should also ensure that research participants who suffer injury as a result of their participation in the neurotechnological research are entitled to free medical treatment for such injury and to financial or other assistance.
- 110.** The exploring of neurotechnological developments for military purposes should be subject to the ethical review requirements of research with human participants. Technological developments used for device control, deception detection and interrogation, as well as war fighter neuro-enhancement are examples of such research developments.
- 111.** The problem of possible misinterpretation of data from neuroimaging is an ethical concern, in that images that suggest a non-standard or exceptional neurological anatomy could be interpreted as being informative and/or predictive. Where predictivity is concerned, similarities also exist between the neurosciences and genetics in regard to population-based data and individual data which form a part of a person's clinical file or records, amplified by issues surrounding the right to know or not to know. The right to refuse to be informed can only be exercised by persons who are in a fit state to express their view and,

failing that, the right can never be exercised by a surrogate person, making a decision in place of another individual.

- 112.** The problem of incidental findings in functional magnetic resonance imaging (fMRI), and the frequency of discovering unexpected anomalies (or the difficulties of interpreting them) may pose ethical challenges such as determining appropriate strategies for communication, and how to handle clinically relevant incidental findings in cases where the person being researched did not express a willingness to be informed about the result. Privacy of such information (and how it is being handled) may also be a concern for participants.
- 113.** The principle of respect for autonomy may be in conflict with that of beneficence when persons subjected to brain imaging research renounce their right-to-know. In seeking to do good (beneficence), a researcher may deem it a responsibility to disclose the potential consequences of incidental findings discovered during brain imaging research, but doing so may be a breach of respect for a person's right to self-determination (autonomy). Research teams in the field of neurosciences should always include clinical medical personnel to interpret incidental findings, and to give research participants the choice of being informed of incidental findings should they so wish. Extra caution should therefore be used in the formulation of the informed consent process. Further, the research project must ensure long-term follow-up especially in relation to invasive procedures.
- 114.** The question of the predictive value of brain images and the possibility to diagnose certain dispositions in the brain (e.g. the likelihood of getting a certain disease) is also of ethical concern. Ascertaining the probability or certainty of such a disposition will be important, since the possibilities of false positives (diagnosing a pathology that is not there) or the possibilities of false negatives (failing to identify or communicate a possibly life-threatening condition) may have major consequences for patients.
- 115.** Findings (incidental or not) that are of a predictive nature about conditions that manifest later in life, may represent a particular challenge if discovered in children. Respect for the children's autonomy and future decision-making sometimes calls for special management of the information that has no immediate relevance for the child's health management. Such special care should be considered, for instance, when no treatment or preventive interactions are available.
- 116.** In the novel field of neurotechnology there is a clear risk attached to excessive reliance on 'single-patient' case reports. Here, there is a tendency towards 'selective reporting', which may be highly problematic. This implies a possible over-reporting of positive results, but can also be responsible for duplication of effort. Research groups may therefore reproduce studies not knowing that similar studies have already been done and failed, which is highly problematic in the field of deep brain stimulation (DBS) due to the risks associated with brain surgery. Consequently, it is critical that all such studies are registered in a public data base (e.g. the WHO International Clinical Trials Registry Platform (ICTRP)).

IV.

○ NEUROTECHNOLOGY AND LAW



IV.1. New dilemmas

117. The development of neuroscience and neurotechnology opens up new dilemmas for human rights, in particular for the right to freedom of thought as the development of new technologies could give access to brain activities from which inferences about individual thoughts can be drawn, as explained before. This therefore challenges the basic assumptions of inalienable mental privacy. Secondly, some results in neuroscience also open up questions about the very legal concept of free will and, therefore, of legal responsibility and liability. If free will does not exist, if it is considered as a human fiction, the individual cannot be blamed for their actions and consequently, he or she is not criminally prosecutable. Thus, our entire legal model could be called into question.
118. These two perspectives of the legal dilemmas derived from the evolution of neurotechnology are related to the distinction made by Adina L. Roskies in her article 'Neuroethics for the New Millenium' (Roskies, 2002), where she proposes a distinction between ethics for neuroscience and neuroscience of ethics. From a legal standpoint, the distinction could be between Law for Neuroscience, in other words, human rights for neuroscience, and Neuroscience of Law.
119. Neuroscience and neurotechnology present themselves as the science capable of revealing to us who we are, the secrets of our biological foundation and of the brain construction of our social, ethical, and therefore legal decisions. Neuroscience entered the free will debate through, among others, the work of neuroscientist Benjamin Libet in his empirical studies of conscious intention to act, studies that have generated widespread discussion and conflicting interpretation.

IV.2. Consent

120. Consent requires a capable mind and a free will. Neurotechnologies offer the potential to interfere (alter, mimic or enhance) with these essential attributes in a unique way. The IBC has already expressed its opinion on the notion and applications of informed consent in several reports, stressing that the main guarantee, traditionally established to protect the autonomy of human subjects in healthcare and research, is consent. Autonomy and responsibility, as well as consent and protection of persons without the capacity to consent, are addressed in Articles 5, 6 and 7 of the Universal Declaration on Bioethics and Human Rights (UDBHR) (UNESCO, 2005).
121. Fast advances in neuroscience and the possibility of identifying the neural correlates of decision-making also open up the possibility of acquiring accurate information about people's competence to consent to specific medical clinical procedures and to medical research. The possibility of creating a reliable neural test of competence, and decision-making competence to consent, opens up many questions: who will choose and set the threshold between what may be a competent or incompetent patient? When must or should this test be applied?
122. An analysis of rational decision-making capacity involves: (i) the ability to understand and retain knowledge, or cognitive content; (ii) the ability to manipulate cognitive content critically; (iii) freedom of will; and (iv) the ability to express oneself. Ordinary people are assumed to be competent to consent; tests are generally only administered if there is a serious doubt as to the competence of particular individuals. Applying standards of decision-making capacity before accepting that someone is competent to consent should avoid false positives, but at the risk of allowing false negatives.
123. There is an international consensus that consent is generally required for medical interventions or for research on health,²¹ however, there are only rare instances of legally binding provisions regarding specific issues of informed consent to neurotechnologies or regarding specific matters such as neural data and privacy.

21 The CIOMS *International Ethical Guidelines for Health-Related Research Involving Humans* (2016) distinctly states in Guideline 9 that 'Informed consent should be understood as a process' and that researchers have a duty (among others) to seek and obtain consent, but only after providing relevant information about the research and ascertaining that the potential participant has adequate understanding of the material facts (CIOMS, 2016). The UNESCO *Universal Declaration on Bioethics and Human Rights* and the Oviedo Convention make clear statements on informed consent including for the protection of those not able to consent (see Articles 5, 6 and 7) (UNESCO, 2005); others are specifically focused on neurotechnology such as the OCDE *Recommendation of the Council on Responsible Innovation in Neurotechnology* (2019) (OECD, 2019)

IV.2.1. Consent to the use of brain data

124. Brain data (also called neural data) include data relating to brain structure and neural activity (see Introduction, paragraph 11). As information about the brain is intimate and private, its improper utilization may cause bias, discrimination, and privacy breaches, and digitally stored neural data could be stolen by hackers or used inappropriately by companies when granted access by the holder or owner of the data. In particular, thoughts are the basis of the freedom of opinion and expression that concerns the public and political sphere and nourishes the functioning of democracy. Furthermore, the brain generates the mood of a person, and so a person's position on a particular matter may be detected and monitored within a clinical setting. Through such monitoring, others may come to know what a person thinks, as well as what they do not think within the perimeters of consciousness, which could constitute an affront to privacy of thought (mental privacy).
125. Customarily (in mental privacy), human beings are able to filter the flow of information and decide which portions they wish to share and not share, in a conscious way. With neuroimaging technology, such mental privacy may be lost, and brain data could be extracted without the person being aware that their information was being read and extracted from them. Decoding of the brain may produce neural data that involve not only conscious thoughts but in fact all brain activity, and this could be subject to commodification. Brain data is a much sought-after commodity which carries the risk of possible de-identification, hacking, unauthorized re-use of information, and digital surveillance. The predictive value of some neural data (for instance, brain imaging) calls for further precautions.
126. Article 3 of the European Charter of Fundamental Rights, on the right to integrity of the person – states that everyone has the right to respect for their physical and mental integrity. This prohibits any manipulation of a person's neural activity without their informed consent. It also underscores the right to preserve one's personal identity and mental activities from any external alteration by third parties unless specific consent is given. However, neurotechnology's potential to intervene in brain activities raises several challenges when it comes to consent.
127. First, informed consent is predicated on the ability of individuals to make free and competent decisions, but in the context of neurotechnology, the technology itself may interfere with such capacity. Moreover, some information may be below the threshold of conscious experience. However, the technology may be able to access such information that is beyond the person's awareness, so that the test of informed consent would not be met. It should be noted that in our previous report on Big Data and Health (UNESCO, 2017a) we analysed at length the various ways to strengthen informed consent in the context of emerging technologies.
128. Secondly, there is a perception that information and understanding prior to consent is often unknowingly incomplete since consenting individuals ignore or have difficulties grasping which and how much data they are giving up, how these data are being used and what might be learned by third parties about these data. This understanding assumes

at the outset the availability of clear and intelligible information to research participants and patients about the collection, storage, processing, and use of personal brain data collected for health or scientific purposes.

129. Third, questions are raised as to whether the traditional informed consent instruments and guidelines are adequate for the uses of neurotechnology and if there is a need to provide additional safeguards to protect confidential information (or what are known as 'informational privacy' and 'brain privacy') given their exceptionally sensitive nature.
130. In fact, questions are raised as to whether brain data should be granted a 'special status'. What makes brain data different from other data? As described in previous sections of this report, brain data are central to one's capacity, self-identity, mood, mental process, etc. Similar questions were raised with genomics data. Furthermore, brain data include an additional dynamic dimension, resulting from each individual's history that sculpts individual brain structure and function. If we consider neural data just as data, they are not much different from other data. But if we consider what type of inference can be derived about the behaviour of a given individual and how such data might be used to change a person's behaviour, then the considerations are completely different from any other data. It should be noted that the General Data Protection Regulation (GDPR) makes a distinction between regular personal data and sensitive personal data. Article 4(1) of the GDPR defines personal data as '*any information relating to an identified or identifiable natural person ('data subject')*'. Sensitive data are 'special categories of personal data' that especially need to be protected. These are classical sensitive data such as one's racial or ethnic makeup, political stances, religious beliefs, trade union membership, (mental) health condition, sexual orientation and criminal files and court proceedings, and the GDPR adds biometric and genetic data. Brain data should be considered as sensitive data.
131. As Ienca and Andorno (2017) explained, the adaptive ability that human rights law has shown in responding to the challenges posed by genetic technology may help to anticipate how this branch of law could evolve in the coming years in response to new issues raised by neuroscience. Since the end of the 1990s, the international community has made significant efforts to address a great variety of issues that result from the increasing access to human genetic data. In 1997, the Universal Declaration on the Human Genome and Human Rights (UDHGHR) was adopted to prevent genetic information from being collected and used in ways that are incompatible with respect for human rights, and to protect the human genome from improper manipulations that may harm future generations. The principles contained in this instrument were further developed in 2003 by the International Declaration on Human Genetic Data (IDHGD), which sets out more specific rules for the collection of human biological samples and genetic data. It is interesting to note that the interaction between genetics and human rights resulted in entirely new rights, such as the 'right not to know one's genetic information', which is formally recognized by the UDHGHR (Art. 5(c)) and the IDHGD (Art. 10), as well as by other international and national regulations. In addition to the recognition of new rights, 'old' rights – such as the right to privacy and the right not to be discriminated against – were specifically adapted to the novel challenges posed by genetics. This close connection between life sciences and human rights was further strengthened by the 2005 Universal

Declaration on Bioethics and Human Rights, which comprehensively addresses the linkage between both fields (Andorno, 2013). This latter document sets out principles that are applicable not only to genetics but to other biomedical and life sciences issues. So, as with the historical trajectory of the genetic revolution and technology in the area of personal data, the ongoing 'neuro-revolution' will reshape some of our ethical and legal notions. In this new scenario, the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity can play a main role.

- 132.** Use of neural data outside the strict context of providing health care to an individual (for instance the research context) raises issues of privacy in relation to the most intimate information about an individual. Sought-after neural data may not be truly anonymous, as a large body of evidence indicates that a data signal cannot be divorced from the identity that produced that signal. So, for example, the electroencephalography (EEG) signal has been demonstrated to be a unique biometric identifier.
- 133.** Within the domain of brain data, there is the risk that de-identified data may subsequently become identifiable, unless the means to protect mental privacy is specifically designed during and within the development of the technology itself.
- 134.** Concerning the consent to share data, alternative systems, such as the opting-out system, are also suggested, the idea being to treat neural data in the same way that organs and tissues are treated in some jurisdictions, for example for transplant purposes, whereby individuals would need to explicitly opt-in to share neural data from any device. 'This would involve a safe and secure process, including a consent procedure that clearly specifies who will use the data, for what purposes and for how long' (Yuste et al., 2017).
- 135.** Even with a renewed approach to consent, neural data from many willing sharers, combined with massive amounts of non-neural data – from internet searches, fitness monitors and so on – could be used to draw 'good enough' conclusions about individuals who choose not to share.
- 136.** Finally, there is a need to review regulatory aspects of other studies outside medical research, such as the case of neuromarketing companies which may run studies involving human subjects without clear informed consent or approval from an ethics committee.
- 137.** Robust protective measures are required in order to preserve the human rights, including autonomy and liberty, of vulnerable human beings. This is especially the case for children, whose brain data could be defining not only in terms of shaping them (their perception as a human being) but could impact their future opportunities (employment, insurance, etc.).
- 138.** Ethical issues surrounding the commodification of 'brain data' (Minielly et al., 2020) will need to be addressed, as will potential outcomes of neurotechnology such as affective computing, neuro-marketing, and human rights. Appropriate governance structures will also need to be developed to ensure adequate regulation of these new developments to protect the well-being and non-exploitation of all humans involved in the process, including for how long (Yuste et al., 2017).

- 139.** Non-medical applications also need better rules of consent, with some being common to rules used for medical applications, and others being adapted to fully respect individual consent in the specific context of use. As an example, in neurogaming, one possibility would be to promote the opt-out of data sharing as the default mode, and to clearly specify who owns the collected data.

IV.3. Neuroscience and human rights: the impact of neuroscience development on the right to freedom of thought

- 140.** The right to freedom of thought and conscience has been proclaimed in all the main international legal regulations. Article 18 of the Universal Declaration of Human Rights proclaims that ‘Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance’ (UN, 1948). These rights are equally provided for in Articles 18 of the International Covenant on Civil and Political Rights (UN, 1966a), 13 of the American Convention on Human Rights, 9 of the European Convention on Human Rights, 8 of the African Charter on Human and Peoples’ Rights (AU, 1981) etc.
- 141.** The right to freedom of thought appeared as a fundamental human right at the beginning of the constitutional revolutions of the eighteenth and nineteenth centuries.²² The right to freedom of thought is considered by the courts as the precondition of many fundamental rights such as freedom of ideology and freedom of religion. Thus, protecting it is a way to guarantee the others. Freedom of thought has two dimensions, the internal, in which the individual has the right to adopt a personal position about life and to judge reality according to their personal convictions, and the external, based on *agere licere*, in which the individual is able to express their ideas or act according to them. As Mill describes it, that sphere includes the inner domain of consciousness, demanding liberty of conscience in the most comprehensive sense, liberty of thought and feeling, absolute freedom of opinion and sentiment on all subjects, practical or speculative, scientific, moral, or theological. This might place it at the top of the order of moral importance; the inner sphere could be paramount in the sense that it is where human freedom begins, for individuals or societies, or in terms of its moral priority and generative significance. Even Mill claims that the freedom to express and publish opinions is ‘practically inseparable’

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America’s founders lauded the importance of freedom of thought: Benjamin Franklin endorsed it in a notable aphorism, contending that without freedom of thought there can be ‘no such thing as wisdom’, and Thomas Jefferson’s sweeping declaration that he had ‘sworn upon the altar of God, eternal hostility against every form of tyranny over the mind of man’. Also, the Constitutional and Supreme Courts of all US States have recognized the relevance of this right. In *Palko vs Connecticut*, 1937, Justice Benjamin Cardozo wrote that some rights such as right to freedom of thought are so rooted in the traditions and conscience of our people as to be ranked as fundamental, and that they compose the matrix, the indispensable condition, of nearly every other form of freedom (Cardozo, 1937a). And in *Steward Mach. Co. vs. Davis*, 1937, Cardozo emphasized that, until now, the law has been guided by a strong common sense that assumes the freedom of the will as a real and working hypothesis in the solution of legal problems (Cardozo, 1937b).

from freedom of thought, and 'almost of as much importance as the liberty of thought itself'. And Rawls proposes that freedom of thought should be included as part of what he calls a fully adequate scheme of basic liberties. Rawls is clear that freedom of thought counts as one of the basic liberties – he lists freedom of thought first among them – and he suggests that those liberties jointly hold the status of a primary good. Rawls suggests that freedom of thought has an essential role in a just political process and maintains that the constitution of a well-ordered democracy must guarantee freedom of thought in order for political liberties to be exercised in a free and informed manner.

142. Therefore, the right to freedom of thought is related not only to human dignity, because human beings are expressive beings which need to order their thoughts as an essential precondition of their freedom of expression, but also to democracy because that freedom is a precondition of a fair and just political system. There is a direct connection between freedom of thought, the rule of law and democracy. Freedom of thought is not only included in lists of primary or cardinal rights and liberties, in notable philosophical treatments; it is often listed first.
143. Traditionally, the internal dimension has not been controversial for the law, and has been proclaimed in all constitutions and international conventions because it was considered a necessary precondition of the external one, as we have seen. For the law, the right to freedom of thought matters because it is the precondition for liberty and freedom of expression and for acting according to one's thoughts. The courts have protected this internal dimension by protecting the means necessary for the individual to develop their own thoughts (for instance, access to publications, media, etc.). The right to freedom of thought has appeared or been invoked in the courts as a way to protect not the thoughts themselves, but the means of ordering those thoughts.
144. With the development of technology, we may one day be faced with machines that can control the brain activities of individuals, in such a way as to control their ideas and thoughts. Will thought be limited by neurotechnology? Will individuals be punished for their thoughts and not only for their actions?
145. Some authors have proposed the idea of developing a new cognitive freedom able to address these new conflicts. A sort of liberty of the mind, to use the words of Charles Fried (Fried, 2007, pp. 95-123, 160, 167). A new cognitive freedom in the sense of also protecting the internal dimension of thoughts. The public powers will then not only guarantee the means to allow the individual to order their thoughts, but also protect the individual from any intrusion into their thoughts. Will this be possible? What legal measures would be needed to implement this new perspective on the protection of the right to freedom of thought?
146. Recent developments in the science of behaviour give some ability to predict and also interfere with an individual's behaviour. However, the impact of such developments is on the actions or expressions of the individual, not on their thoughts. Through a WhatsApp message, for example, we can understand what an individual is expressing, but it is not possible to find out what they are actually thinking, unless we can access their thoughts.

While it is well known that humans do not always act in strict correlation to their thoughts, we have also always enjoyed the guarantee that our thoughts are hidden from third parties. This can be considered one of the most vital aspects of our dignity and, above all, an important rule of social coexistence. Our dreams and opinions make us free, considering that they are preserved from control by others and, because of society's organization, we are able to think whatever we want while ensuring our actions adhere to social norms. Our cognitive capacities are also the basis of our relationship to others, and are essential for building a human society.

- 147.** The improvement of new technologies and apps in the area of personal computers and the internet has brought the need for new regulation of the new personal data. We might propose similar regulations, a new 'thought protection', a new *habeas cogitandi o mens*, considering the development of new technologies which are able to control not only our actions or decisions (current personal data), but also our internal thoughts. Informed consent, proportionality and different forms of confidentiality guarantees such as anonymity would again play a major role. A right to keep one's thoughts and personality away from any kind of intervention aimed at damaging individual liberty could be developed based on the principles and rules of data protection.

IV.4. Freedom of thought is not identical to cognitive liberty

- 148.** As stated earlier, some authors consider that the current legal model developed for data protection and biotechnology is useful in addressing some of the new issues and conflicts posed by neurotechnology from the human rights perspective, but it is not enough, because some of the issues and conflicts are new and different from those previously addressed by the law. Consequently, we should develop and include new rights and guarantees. In a major initiative, some have proposed the formulation of a new right to guarantee an individual's cognitive liberty in the new context of neurotechnology development. This is an adaptation of traditional freedom of thought to the new context, in which something internal could be transformed into something controllable by external tools. Are we talking about the same right in a different context?²³ Negative rights impose obligations on governments and other citizens to refrain from interfering with the owner of the right. By contrast, a positive formulation of cognitive liberty would help make the existing neurotechnologies widely available to anyone who wants them.
- 149.** If we analyse the different definitions of cognitive liberty, we will find a relationship between this right and enhancement, in the sense that the new neurotechnology will be able to improve individuals' mind power. Looked at this way, we are talking about something directly related to the 'transhuman' movement and its proposal to take advantage of scientific evolution to develop 'better' and more powerful human beings. Formulation in this way, this new right will have positive meaning, and not be a mere freedom.²⁴ It is not a mere freedom relating to dignity and privacy in the sense of 'leave my thoughts alone', but something closer to a right to control decisions made about one's own brain. This right includes not only a negative aspect but a positive one in the sense of giving the individual the faculty to accept the use of neurotechnology tools to improve and therefore enhance, their brain.
- 150.** In this definition, there is something more than privacy – meaning that our thoughts must remain private until we decide to share them, as a legal guarantee protecting individual freedom and self-determination from the State and other subjects, but particularly from the State or commercial entities: a sort of protection from the coercive and non-consensual use of neurotechnology. This goes further than autonomy, with the idea that every human being must be able to think independently and use the full spectrum of

²³ Paolo Sommaggio et al. (2017) explains that cognitive liberty is a very complex concept due to its multi-dimensional features, and that rights and guarantees must take account of the various contexts of application.

²⁴ This is the position of Christoph Bublitz, who suggests that the right to cognitive liberty should be the central legal principle guiding the regulation of neurotechnology, guaranteeing the right to alter one's mental states with the help of neurotools as well as to refuse to do so (Bublitz, 2013). For Bublitz, when we talk about cognitive liberty, we are talking about a right to mental self-determination, which guarantees individuals sovereignty over their minds.

their mental faculties. In addition, cognitive liberty includes a third sphere, choice, which requires that the capabilities of the human mind not be limited.

- 151.** On the other hand, cognitive liberty might be understood as a negative right and not a positive one (Ienca and Andorno, 2017). According to this understanding, cognitive liberty is a prerequisite of all rights focused on neuro-aspects. Cognitive freedom is a new form of freedom of thought that takes into account the power we now have, and increasingly will have, to monitor and manipulate cognitive function (Lavazza, 2018). Faced with potential new threats to mental integrity from neuroscientific techniques, attempts have been made to introduce new human rights, specifically aimed at safeguarding the right to cognitive freedom, the right to mental privacy, the right to mental integrity, and the right to psychological continuity. It is also important to protect brain data that can be used for the (more or less precise) prediction of a person's behavioural patterns through their neural connection and activation patterns. In fact, such information could be used for forms of prevention/discrimination based on an individual's hypothetical attitudes, or even to implement forms of forced re-education or compulsory moral bioenhancement (Baccarini et al., 2017).

IV.5. Neurotechnology, law and democracy

152. The development of neuroscience and neurotechnology not only affects the concept of freedom of thought as a human right, but also the legal and judicial system, which is based on the idea of free will. The only justification for criminalizing and punishing some actions by individuals is their free will. Without the concept of free will, the law cannot be understood and accepted.
153. The Libet experiment opened up an interesting academic argument about the future of our legal system and, specifically, about our criminal law model based on free will. Significantly, some authors have suggested that neurosciences inevitably lead us to consider free will as a pure illusion and therefore as a kind of necessary social convention. This appreciation is very problematic and is not unanimously accepted even within the scientific community (c.f. G. Edelman, E. Kandel, A. Damasio, St. Dehaene, etc.). Moreover, many philosophical works tend to establish the contrary (M. Merleau-Ponty, F. Varela, J. Habermas, etc.).
154. Law is based on social conventions and not only on science. Science is important for the law because it provides elements for making legal decisions, but science is not the foundation or essence of our legal systems. For instance, the development of genetics has been very important for the investigation and trial of crimes.
155. The example of democracy could be a good one for our current debate. Democratic systems are based on social conventions, not on scientific evidence. In democratic systems, scientific measurement of the intelligence of the voters is not relevant, except for some cases of mental incapacity to make decisions. Each voter is entitled to one vote without consideration of their intellectual preparation or mental capacity from a neuroscientific perspective. All are equal at the ballot box and all are also equal in the legal system, for similar social and anthropological reasons. Such legal systems are based on freedom and equality among citizens, and the idea that such social conventions might change in the context of a huge improvement in neuroscience and neurotechnology is still in the realms of science-fiction.
156. The reasonable organization of human social life is not possible without the reciprocal recognition of freedom. Improved knowledge about neurological processes is necessary to improve the functioning of law and especially criminal law, but it is difficult to believe that it could replace it in our societies.
157. Therefore, we can address huge developments in neuroscience and neurotechnology without devaluing the role of law and justice. Neuroscience will provide law with important new scientific evidence, as genetics did, mainly in the area of criminal capacity, but free will

as a social convention will still be there. Neuroscience will play, and is currently playing, a role in the field of evaluation of mental capacity but does not dismiss free will as a foundation of the law. Brain imaging techniques, for instance, might possibly contribute to more evidence-based decisions in criminal justice, from investigation and the assessment of criminal responsibility, to punishment, rehabilitation of offenders, and the evaluation of their risk of recidivism. The tools offered by neuroscience could potentially also play a role in civil law procedures, for example, in the assessment of an individual's capacity to contract, or the severity of the plaintiff's pain in compensation claims. New and more reliable lie detection technologies based on our knowledge of the brain's functioning might help to assess the reliability of witnesses. Memory erasure of recidivist violent criminals and of victims of especially traumatic offences (e.g. sexual abuse) is also mentioned as another possibility opened by our new knowledge of the brain (Goodenough and Tucker 2010; Ienca and Andorno, 2017). Neuroscientists can play an important role in court as expert witnesses, but they do not decide cases. The judge will always make the decision.

- 158.** The main question now could be whether the human irrationality we have accepted in many areas, such as justice and democracy, is nearing its end. In any case, it is important to underline that irrationality is extremely human, and as humans we need something more than science. Social conventions and solutions play an important role in our societies, apart from science. A new paradigm based on science alone is doomed to fail, as positivism did some decades ago (Greely, 2009).²⁵ And as Kant said many centuries ago, a merely empirical doctrine of right (we might add 'of law') is a head that might be beautiful to look at, but unfortunately it has no brain.
- 159.** Thinking that the brain/morals/law relationship is everything can lead us to forget that the measure of law, the very idea and essence of law, is human, and human nature is the product not only of a very complicated mixture of genes and neurons but also of experiences, values, learning and influences from our equally complicated socio-cultural life.
- 160.** Habermas (2008) argues that the categorical error we would be making in trying to explain the performance of the human being only from a neurobiological perspective is that the essential feature that defines and differentiates human action is not explained by reference to causes such as the behaviour of the apple falling from the tree. Human action results from motives, intentions, plans, and reasons; and the reasons for action arise from individual experience and social interaction and communication. The Libet findings about the unconscious brain activities involved in decision processes do not change the definition of the decisions that we make in a moral or legal framework.
- 161.** Neurotechnology is a revolution, like all scientific revolutions, in tools. These tools are giving us the ability, for the first time, to look inside living, healthy human brains and to

²⁵ Henry T. Greely concludes in a very graphic way, 'I have neuroscientist friends who say neuroscience is going to prove that humans have no free will and that, as a result, our criminal justice system will dry up and blow away. I doubt it. Even if neuroscientists convince themselves that humans have no free will, I doubt they will be able to convince the rest of us. I am not sure we have the free will to truly believe, and act as if, we do not have free will. I predict we will continue to punish people as if they have free will. And, of course, we would still have a criminal justice system even if we did not believe in free will'.

see what is happening. And they are giving us the chance to begin to correlate the physical states of the brain, revealed by these tools, with the states of the mind that are produced by those activities (Greely, 2009). As mere tools we should not transform them into a new philosophical, ideological or legal paradigm. Tools are developed to serve human beings, not to transform our social conventions which have been the real driving force in developing a world based on the relevance of human rights.

V.

GOVERNANCE OF NEUROTECHNOLOGY



V.1. Responsible innovation

- 162.** As described in the previous sections of this report, neurotechnology has the potential for tremendous benefits in health, education and social relationships, but also holds the potential to deepen social inequities, to harm individuals' privacy and to provide methods of manipulating individuals (such as technologies of persuasion and personality-altering technologies), and consequently the potential to challenge some basic aspects of human dignity, such as privacy of mental life or individual agency. Such challenges call for a responsible approach to research and innovation.
- 163.** Regulation of science and technology is late if it merely responds to concrete situations generated by technologies already available or even widely applied. For this reason, it is necessary to anticipate the effects of implementing neurotechnology, using scenarios in which society, science and future technologies and how they will interact are imagined (the so-called 'sociotechnical imaginaries'). As with all emerging technologies, neurotechnology development needs an 'ethical-by-design' approach. The spectacular development of neurotechnology as well as new biotechnologies, nanotechnologies and ICTs makes machines more and more humanoid, and people are becoming more connected to machines and AI, indicating a pressing need for anticipatory governance.
- 164.** Indeed, fostering responsible innovation in neurotechnology (OECD *Recommendation on Responsible Innovation in Neurotechnology*, 2019) requires clear guidance on 'how to identify and anticipate the broader impact of neurotechnology on society; and how the potential of novel neurotechnology is communicated to the public to both inform and to avoid hype' (Garden et al., 2019). Notably, 'neurohype and false promises can give rise to mistrust and unintended social effects' (Garden et al., 2016). Consequently, one of the relevant policy considerations that requires attention is the need to ensure a 'strong "technological push" of brain science towards addressing pressing societal needs', which can be achieved through a public deliberation approach across sectors (Garden et al., 2016).
- 165.** Differences in the definition and framing of Responsible Research and Innovation (RRI) have made it challenging to apply the RRI framework in governing emerging technologies such as neurotechnology (Garden et al., 2016). However, there seems to be agreement that the RRI framework is designed to enable stakeholders to collectively discuss avenues for advancing societal goals through technology (Garden et al., 2016; Owen et al., 2013).
- 166.** The three questions that should guide the RRI process as suggested by Garden et al. (2016) are: first, who benefits, how, and what are the (potential) costs? Secondly, what are the uncertainties and what are the potential implications if we are wrong? Thirdly, who controls access to the science and the technology, and under what conditions? Addressing these questions requires continuous engagement with relevant stakeholders.

- 167.** In order to protect the dignity of people and humanity as representing the group to which we belong, which is distinguished by freedom, it is of capital importance to formulate appropriate regulations for neurotechnology. In accordance with principles of good governance of technologies, openness, transparency, honesty and accountability, such regulations might include a personal oath in which each inventor, producer, and seller of neurotechnologies undertakes to use them and offer them for the benefit of users in accordance with their human rights. A governance framework could also identify neuro-rights, which should be set forth in a future 'UNESCO Universal Declaration on the Human Brain and Human Rights' that should be drawn up as a UNESCO Universal Convention inviting governments to establish a specific legal framework for such rights to be applied, enforced and sanctioned.
- 168.** One major concern is the risk of new inequalities resulting from neurotechnology, particularly those arising from, and adding to, social inequalities. Specific mechanisms should be used in this regard such as free licensing for developing countries or fostering participation in patent pools to make products affordable. Responsible transfer metrics could include consideration of social benefits and impact (e.g. free licensing for developing countries), equity (e.g. patent pools), and anticipatory governance (e.g. as part of business plans), and could adjust incentives and transfer contracts accordingly (e.g. requiring RRI boards for start-ups) (Garden et al., 2019). These aims could be achieved through optimal use of suitable competition policies, which have been hailed as driving innovation and access. Competition policies can be used to eradicate restrictive conditions in medical technology licensing and abuse of intellectual property rights by holders (WHO, WIPO and WTO, 2013).

V.1.1. Engaging with the public

- 169.** Responsible innovation in neurotechnology must be a collaboration between science and society (Garden et al., 2019). In the process of developing neurotechnologies, it is essential to include the perspectives (needs, concerns and experiences) of the people who will use them. Education regarding what neurotechnologies are and what effects can be expected or feared is obviously a basic need. But education is not enough. Neurotechnology development requires engagement with the public, which should be focused on two-way, rather than one-way, communication with the public (Stilgoe et al., 2014). Consequently, engagement must be made inclusive by embracing public values in the innovation and development process (Garden and Winickoff, 2018). Innovators in neurotechnology should therefore consider the social value and impact of the technology by ensuring responsible innovation. This requires an evaluation of the ethical and social aspects of the technology. Engaging the public 'is critical for developing trust and trustworthiness with end users, and can help tailor emerging technologies better to the needs of those they are designed to help' (Garden et al., 2019). This also helps to eliminate unrealistic expectations that can erode public trust.

- 170.** Educating the public on the possible cognitive and emotional effects of neurotechnology is a pre-requisite to public engagement. However, faced with such cutting-edge technology, bridging the knowledge gap between citizens and experts can be quite a challenge. Furthermore, the distribution and access to neurotechnology, both from the point of view of their access and from the point of view of the knowledge needed to use them, is unequal between countries and regions of the world and also within the same country due to social stratification (the so-called 'technological divide'). Education should target various publics, including teachers. UNESCO could provide some training and capacity building support.

V.1.2. Engaging with the industry

- 171.** Key players from the private sector as well as start-ups are at the forefront of neurotechnology innovation. They serve all sectors of societal activities such as health, education, military, gaming and entertainment. Consequently, the private sector should be involved in responsible development of technology as soon as possible, namely at the preliminary and early stages (Garden et al., 2019).
- 172.** Obviously, it is expected that individual companies must be responsible for their neurotechnology products, and make responsible claims about them (McCall et al., 2019). Neurotechnology development must be guided by standards, good practices and ethical norms, resulting from the legal and ethical regulation in the field. In particular, the EU Medical Device Regulation (26 May 2021) increases the accountability of all stakeholders and focuses on the entire production process of devices, not just on their marketing:
- a) Vigilance and post-marketing surveillance: Medical device manufacturers must have plans for post-marketing surveillance, continuous evaluation and improvement.
 - b) Reinforcement of the responsibility of manufacturers, importers and other actors involved in marketing for regulatory compliance.
 - c) Reinforcement of verification processes and obligation to submit internal verification programmes to the regulatory authority of each European country.
 - d) Identification of devices: obligation of traceability.
 - e) Information: Manufacturers will be required to provide a clear and understandable summary of the safety and clinical performance of devices.
 - f) Clinical evaluation, post-marketing follow-up, clinical research: stricter rules.
- 173.** However, neurotechnology raises such a unique set of societal and ethical issues that it requires further proactive actions beyond regular product warranties.
- 174.** Such good practices include having harmonized standards for neurotechnology innovation to ensure a positive impact on health and society. This is because 'the standardisation of neurotechnology system specification and interoperability helps communication and collaboration across major brain research initiatives and the private sector' (Garden et al.,

2019). Standardizing personal brain data collection, curation, and sharing are essential for driving new discovery and obtaining broader value from the data (Garden et al., 2019).

175. Developing gender-neutral products and ensuring inclusive innovation are among the good practices that ought to be considered (OECD *Recommendation of the Council on Responsible innovation in Neurotechnology*, 2019). Privacy by design should also be a backbone of any neurotechnology device, given the highly sensitive nature of brain data.
176. Finding an appropriate balance between regulating such best practices and stimulating responsible and ethical innovation is key. To achieve this, it is suggested that one effective approach might be for the professionals involved in designing neurotechnologies (engineers, programmers, etc.) to commit to an oath of responsible innovation bearing some similarities to the values upheld by the Hippocratic oath. If such an oath is supported, appropriate structures should be developed to review and oversee its application.

V.2. Public-private partnership

- 177.** In recent years, research and development have often been driven by public-private partnerships (PPPs). In the current era of 'Open Innovation', industry looks to partner with institutions of higher learning (which perform publicly-funded basic research) for useful inventions, after which industry will collaborate further in research, development and commercialization of the invention, resulting in shared intellectual property rights. Neurotechnology is an area that has the potential to exploit this PPP. The invention and subsequent development and commercialization of the Magnetic Resonance Scan (MRI) and the Positron Emission Tomography (PET) scan are good examples of previous PPPs. PPPs offer tremendous opportunities for companies to make products ranging from medical equipment to industrial and consumer products. Among these are neuroimaging and other neurodevices, many of which are designed to collect brain data that can be used to treat illnesses such as Parkinson's disease and debilitating conditions such as blindness, and to further our understanding of brain function. Brain-computer interfaces are areas of research which are not only important for medical purposes, such as repair of sensory loss, but also impact the development of artificial intelligence. They are also important for learning, developing our understanding of individual and group psychology, and marketing purposes.
- 178.** On the whole, while the private sector has the goal of making profits from investment in products and data from neurotechnology, the scientists and engineers in the public sector aim to gain knowledge on the physiology of the brain and neural systems not only for academic purposes but also to serve the public in providing tangible solutions in neurology, psychiatry, cognition, learning, social services and other areas. Partnerships can be a win-win situation and many have been formed between the public and private sector, such as the BRAIN initiative, launched in 2003 with the US National Institutes of Health as the leading member, which aims at achieving a dynamic picture of the brain that shows how individual cells and complex neural circuits interact in both time and space. It provides funding opportunities for such research areas as devices for recording and modulation in the human central nervous system, next-generation human brain imaging and the ethical implications of advancements in neurotechnology and brain science. Around the world, a number of large research programmes on neurotechnology are funded by governments with input from the private sector. These include the Human Brain Project launched by the EU, the Blue Brain Project initiated in Switzerland, the Brain/MINDS project launched by Japan, the China Brain Project, and several other initiatives now included under the auspices of the International Brain Initiative (IBI, 2016). These projects largely aim to use information and communications technology, artificial intelligence and biomedical and related technologies to understand and modify brain functions and neurotechnology in general, and make use of the knowledge gained.

- 179.** Public-private partnership can potentially yield further benefits to consumers and the general public. With the knowledge gained from such partnerships, consumers and the general public can benefit from better prevention and treatment of brain and other neural disorders, better learning capabilities, better human-human and human-machine communications, and other benefits. These partnerships can provide much-needed investment for start-ups to thrive in neurotechnology innovation. It is also through public-private partnerships (PPPs) that we can ensure 'new approaches to information sharing, intellectual property (IP) management, public engagement, and incentivising open science and responsible innovation' (Garden et al., 2019). Additionally, such partnerships can help in tackling responsibility issues (Garden et al., 2019). However, the balance between public and private interest is crucial in determining the direction of progress of neurotechnology, and also in safeguarding against misuse of the technology.
- 180.** In accordance with the principles of accountability and responsible regulatory stewardship, protection of personal identity and personal data are paramount. Good governance is necessary if the private sector is to be entrusted with the task of collecting individuals' brain data. It is also necessary for regulating the commercialization of brain data; ensuring that the recording and modulating of human thoughts and other brain processes are done ethically; regulating the use of data generated from public-private partnership; the use by the public sector of the advances gained from public-private partnership; safeguarding the collection and collation of brain data from the public by governments and other entities; allowing public-private partnerships to access such data; and modulating public and individual brain processes. The issues raised by George Orwell in his novel *1984* are most pertinent in this regard, and these and related questions form the core of the ethical considerations in public-private partnerships in neurotechnology.
- 181.** It is important for both public and private sector researchers to be aware of, actively engage with, and address the potential conflicts of interest and other ethical and legal issues, which include: inadequate risk assessment on misuse of technology and data, premature commercialization, preferential benefits to private sector partners at the expense of the public, commercialization of such technologies as brain monitoring and behaviour modification, and ethical and legal concerns about research and products/procedures resulting from the partnership.
- 182.** The public, too, should be aware of the potential consequences of various public-private partnerships for neurotechnology, which may have a potential impact on their lives and livelihood, ranging from use of the technology in monitoring and controlling behaviour, manipulation of mass psychology, influencing the direction of education, and influencing political outcomes. Civil society organizations and pressure groups formed by members of the public can help to interrogate the aims and working methods of researchers and institutions, including those involved in public-private partnerships, and should participate in debates on ethical aspects of neurotechnology, to ensure good governance and help answer the questions concerning ethical conduct in neurotechnology (Garden et al., 2019).

VI.

RECOMMENDATIONS



183. In the framework of this report, we have identified the benefits that may result from the development of neurotechnology, but also some fundamental human characteristics and their associated human rights that might be challenged by this technology. These include:

- a) **Cerebral/mental integrity and human dignity.** The growing neurotechnological possibilities to modify the brain, and consequently the mind, in an invasive and pervasive way, serve to reinforce the idea that the value of the person ought to be considered as a whole.
- b) **Personal identity.** This refers to our ability to think and feel for ourselves, regardless of how neurotechnology is applied. It is possible that when brains are connected to computers, an individual's identity can become diluted, in part because algorithms help them make decisions and can consequently blur the participation of the individual-self. Thus, we need to preserve individuals' control over decision-inducing neurotechnology.
- c) **Freedom of thought, cognitive liberty and free will.** Brain activities allowing free will are highly connected with personal identity. External tools that may interfere with our decisions can call into question, or even challenge, an individual's free will, and consequently an individual's responsibilities. In this way, neurotechnology could affect freedom of thought, decision-making and action. Taken together, these could have a profound impact on justice systems and social organizations.
- d) **Mental privacy and brain data confidentiality.** There are specific issues that can arise from brain data collected by neurotechnology. Mental activity is the most intimate part of the human being, and should be protected against illegitimate interference. Neurotechnologies can acquire a lot of data from users and these data need to be protected. Some aspects of these data are already subject to regulation: health data and personal data, at least in jurisdictions that have adopted laws such as the GDPR. This is illustrated by the following:
 - i) The specificity of brain data lies in the inferences that can be drawn from their analysis about actual consciousness, emotional state or even thoughts. It is thus essential to protect the absolute confidentiality of this particular kind of data and the inviolability of the mind where they nested.
 - ii) The inferences that can be drawn from brain data analysis may also enable prediction of an individual's behaviour. Big data analytics enable privacy-sensitive inferences to be made from non-sensitive data. Here we have identified the risk of neurosurveillance, monitoring, for example, attentional engagement or awareness at the workplace or at school. Thus, brain data confidentiality must be protected. Brain data should be considered as sensitive personal data.
- e) **Distributive justice.** Neurotechnology can bring benefits for humans, particularly for neurological and mental health, but also in several other fields such as education. However, their availability and accessibility may present a problem, if they increase inequalities by conferring privileges on a few who may have access while excluding

those who do not have access for economic, social, cultural, moral, religious or geographic reasons. It is thus necessary to ensure well-regulated and fair access to these technologies.

- f) **Discrimination/bias.** The algorithms driving most contemporary neurotechnologies, working according to an average or standard, classify the individuals from whom the data are being collected into groups, thereby reinforcing prejudices and biases that may result in discrimination and enhance vulnerability of individuals and groups. It is necessary, then, to detect bias and prejudice in classification algorithms and devise ways to remove them, before implementing AI and neurotechnologies in the broader population.
- g) **Misuse.** This issue concerns unauthorized or coercive use of neurotechnology, such as a breach in cybersecurity in the case of fraudulent access to neural data. Third-party interference in device function for non-benign purposes or malicious hacking are also serious concerns.
- h) **Augmentation/enhancement.** Some neurotechnologies are being developed with the purpose of enhancing cognitive capabilities. There are serious ethical questions regarding how this kind of 'enhancing neurotechnology' can be used appropriately, given the lack of safety and efficacy, and the challenges related to human dignity, autonomy and justice.
- i) **Interests of the child.** It is necessary to pay special attention to the ways in which neurotechnologies could affect the brain in childhood and adolescence. At this rapidly changing and life-defining period of development of the brain, it is crucial to preserve the future rights of children and adolescents to make autonomous decisions, as well as their privacy. Special considerations and specific guidelines and regulations must be implemented when neurodevices are used in healthcare on children and adolescents, or by them for personal use such as neurogaming or neuroeducation.
- j) **Informed consent.** Considering the potential for changes in perception of personal identity and cognitive abilities, additional safeguards and robust, context-specific informed consent procedures must be followed in view of the nature of the technology.

184. Considering these challenges, several options were discussed by the IBC to recognize and protect neurorights:

- a) Add protocols to international treaties, such as the Universal Declaration on Human Rights, to address challenges posed by neurotechnologies.
- b) Reinforce the Universal Declaration on Human Rights, considering that neurotechnology challenges existing human rights and that new guarantees will be required based on the potential for infringements.
- c) Draw up a New Universal Declaration on Human Rights and Neurotechnology.

- 185.** The IBC considers that neurorights embrace certain human rights that are already recognized in national laws, international laws, international human rights instruments and other consensus documents. These rights rest on the recognition of the basic rights of all individuals to physical and mental integrity, mental privacy, freedom of thought and free will, and the right to enjoy the benefits of scientific progress, and on the recognition of the need to protect and promote these rights with regard to the application of neurotechnology. They also include the right to decide freely and responsibly on matters related to the use of neurotechnology, without any form of discrimination, coercion or violence.

Recommendations of the IBC to UNESCO

- 186.** This report reveals the multidimensional impact of the rapid advancements in neurotechnology, shedding light on both positive and negative aspects. Based on the analysis provided in the report, UNESCO should pursue actions to implement its recommendations. To this end, the IBC calls on UNESCO to use its unique global mandate in the ethics of science and technology, and its multifaceted expertise, to address the challenges highlighted by this report:
- a) To provide new insights into the interpretation and application of existing human rights instruments by legislative bodies and courts in relation to the new challenges;
 - b) To propose the adaptation of existing human rights instruments and the proclamation of new human rights; and
 - c) To organize global dialogues in the field of human rights towards building a consensus on the nature and substance of neuro-rights.
- 187.** In order to keep pace with these fast-advancing technologies, particularly in terms of regulating their application in a wide range of domains, UNESCO could convene a multidisciplinary group of experts to develop a policy-oriented governance model, to monitor progress in the field, and to examine whether the issues raised are effectively covered by the existing legal frameworks. This governance model would build on the existing human rights architecture and incorporate the relevant principles identified in this report, paving the way towards the eventual elaboration of a new normative instrument on neurorights.
- 188.** The IBC emphasizes that the following considerations are essential for the elaboration of such an international instrument:
- a) All humans have a right to protection of their brain activities regardless of race, gender, socio-economic status and cognitive abilities.
 - b) Brain data obtained from, with, or via neurotechnology must never be used for surveillance or profiling without proper informed consent, and never for potential discrimination based on cognitive or other mental features.

- c) Uses of neurotechnology by state and non-state actors should be scrutinized for possible violations of human rights.
- d) Promoting dissemination of information, education and dialogue on neurotechnology is of paramount importance to ensure responsible and ethical use.

189. UNESCO should lead efforts in cooperation with the other relevant international organizations. UNESCO may consider establishing a global virtual forum to share best practices and innovative ideas to maximize the benefits while minimizing the risks associated with the use of this technology.

Recommendations of the IBC to Member States

190. On the basis of constitutionally recognized human rights, IBC encourages Member States to guarantee neurorights. Granting neurorights a positive status will empower citizens to claim respect for these rights as well as empowering Member States to provide appropriate legal frameworks for the production and use of neurotechnology.

191. Consequently, the IBC calls on Members States to:

- a) Ensure that their fundamental laws clearly recognize and guarantee the physical and mental integrity that allows people to fully enjoy their personal identity, and the right to act in a self-determined manner, and that the law alone may establish the requirements for limiting this right.
- b) Adopt laws to regulate the use of neurotechnology, such as recording of brain activities, especially when its purpose is not for scientific research, medical needs or the administration of justice.
- c) Promote education, engagement and empowerment on emerging technologies and particularly on neurotechnology. Recognize that public education, engagement and empowerment (EEE) is critical for optimal decision-making and societal acceptance of neurotechnology.
- d) Protect the right of individuals and members of a group or institution such as schools, companies or any other to refuse the use of neurotechnology and not be excluded or devalued for doing so. Alternatives should be sought for them. Nobody should be forced to accept neurotechnology that may alter their sense of self or personal identity as well as their capacity for self-determination.
- e) Protect the right to have access to alternatives that are not neurotechnology-based and that offer the same effectiveness.
- f) Protect the right not to be socially bombarded by neurotechnology marketing in order to promote a supposed human improvement.
- g) Address the need to increase the traceability and auditability of data-driven inferences, due to the current poor regulation of direct-to-consumer neurotechnology.

- h) Address the need to increase oversight of easy-to-co-opt unsupervised neurotechnology applications.
- i) For the same reason (current poor regulation) and often deficient information, address the need to inform the consumer of neurotechnology about the possible risks of direct and/or indirect influence on their privacy; the possibilities and risks of data sharing (when applicable); the risks of non-therapeutic enhancement as well as information about what neuromarketing is and what are its risks. Ensure that pertinent information emanating from neurotechnology developments/research is given timely publicity in clear and culturally appropriate language. Unfair or deceptive business practices should be prohibited.
- j) Help facilitate broad and inclusive discussions on the topic of neurotechnology at the local, national, and global levels.
- k) Develop equitable access to neurotechnology, not only in the medical field but also in areas of education and other fields of human development.
- l) Member States should consider laws or other mechanisms to regulate the use of paediatric neuro-enhancement tools in children. Neurotechnology should be carefully studied and assessed for its safety and efficacy before it is used on children.

Recommendations of the IBC to the research community

192. The IBC recognizes the tremendous benefits that may arise from the development of neurotechnology in understanding how our brains work at an individual as well as a collective level, and alleviating the heavy burden of neurological and mental disorders. The IBC thus strongly supports the responsible development of research on neurotechnology. Consequently, the IBC calls on the research community:

- a) To develop a Code of Conduct for responsible research and innovation in neurotechnology. Such a code should be neurorights-based within the context of multidisciplinary integration of research teams, involving experts from law/ethics, natural sciences, engineering, neuroscience and civil society representatives. Evaluations can only be made efficiently once each protocol and procedure is carefully defined, according to validated selection of the evaluation instruments and the inclusion and exclusion criteria.
- b) To address the specific challenges that may arise with regard to informed consent and protection of privacy issues (for example preventing re-identification based on facial recognition from brain scan images or default mode analysis of brain activity). These challenges include finding ways to strengthen informed consent where prospective research participants have cognitive impairment/disturbance or where the neurotechnologies may interfere with the individual's capacity to give further informed consent to continue the research. Research participants should be fully informed of

the possibility of an intervention affecting their sense of self, personal identity, or self-determination.

- c) Researchers in neurotechnology should be encouraged to adhere to the principles championed by the 'Open Science' movement, in order to ensure experimental rigour, data reproducibility of research approaches, and accountability, thus accelerating discoveries and the development of beneficial therapeutic interventions and devices. Considering the potential re-use of the data and their availability to a large community, researchers should also establish clear confidentiality and privacy policies. As part of the information provided to participants in the research during the informed consent process, the possibility that their data might be shared in scientific exchanges, with due regard for privacy and individual anonymity, should be explained.
- d) To raise awareness of researchers about dual use. We recommend that measures must be in place to protect against neurotechnologies being open to dual use.
- e) Researchers should be encouraged to develop measures to counteract bias. This could include ensuring diversity in both the research team and the participants involved in research, as well as creating pluralistic focus groups for continuous feedback throughout the whole course of the technological development. For the sake of transparency, researchers and developers must also communicate biases to both the public and peers. Ensure that neurotechnology does not instil prejudices through algorithmic means.
- f) To introduce and promote responsible and accountable neurotechnology which has an emphasis on algorithmic transparency, security and privacy. Thus, its development and outcomes are respectful of human rights standards while at the same time promoting inclusion and the participation of diverse and representative human groups and experts.
- g) To introduce and promote responsible and accountable neurotechnology with an emphasis on development according to human rights standards, with the participation of diverse and representative human groups, taking into account privacy and security by design while being accountable for its outcomes and allowing proper auditing processes.
- h) To train and increase the awareness and capacities of research ethics committees to assess and monitor neurotechnology research projects.

Recommendations of the IBC to the industry

193. Since the industry is at the forefront of innovation in neurotechnology, responsible innovation is required and IBC makes the following recommendations:

- a) Based on OECD Recommendation 457 but not restricted to the health sector, a Code of Conduct for responsible research and innovation in neurotechnology is required

to enhance security standards of neurodevices, algorithms and data-sharing infrastructures and develop a user-centred design.

- b) Algorithmic transparency is needed to ensure that algorithms are fair and amenable to ex post and ex ante inspection, and avoid the reinforcement of discrimination through gender, racial, sexual orientation or sexual identity bias.
- c) Data privacy transparency: measures must be taken to secure collected data, and determine its use or re-use. If AI is applied there must be guidelines on the purpose, the kind of analytics and the methods used to train systems and inform decision-making processes. One example is imaging. Neuroimaging often needs careful anonymization, to make the face (profile) unrecognizable.
- d) Data use should promote opt-out as the default mode.
- e) Treatment of data must be transparent. Since each individual remains the owner of their neural data, transparency should be ensured in using data generated from neurodevices, so that individuals know if and how their data may be used, re-used or transferred, and to ensure data provenance. No brain data should be shared without due informed consent and an appropriate legal framework.
- f) Avoid giving users false expectations and do not make unfair promises.
- g) Develop gender-neutral products ensuring inclusive approaches.

Recommendations of the IBC to the media

194. Since the media, through its various channels, has the responsibility to raise public awareness of new emerging technologies, it also has the responsibility to help the public understand neurotechnology, and report fairly on its benefits and its challenges. The IBC calls on the media:

- a) To inform the public on some misconceptions about neurotechnology associated with new emerging technologies, by disseminating and verifying the accuracy of the scientific information given. Thus, the media can help the public in deciding what can and what should not be accepted. This will be especially beneficial in low-income countries where there is a high percentage of illiteracy, and a lack of access to Internet.
- b) To address the community in their appropriate language, thus helping them understand what they could not understand through other channels.

Recommendations of the IBC to the public

195. The IBC calls for the development of improved and more systematic national frameworks for facilitating meaningful Education, Engagement and Empowerment efforts related to neurotechnology and thus the IBC calls on the public to:

- a) Emphasize that each individual is the owner of the data collected from him or her, and that it can be used, published or traded only in exceptional circumstances and only with explicit informed consent.
- b) Become aware of potential benefits and risks in neurotechnology, especially where it impacts individual integrity, influences perception, or induces decision-making, and engage in public debate and other actions to examine potential abuses.
- c) Become engaged in issues of neuroethics and neurorights, individually or through the formation of interest groups.
- d) Use legal means, including laws and public pressure, to prevent potential abuse of neurotechnology by the government, public agencies or the private sector.

GLOSSARY

This glossary is based on existing definitions and aims only to provide a general understanding of the language and terminology used in the report.

AFFECTIVE COMPUTING

Affective computing is the study and development of systems and devices that can recognize, interpret, process, and simulate human affects. It is an interdisciplinary field spanning computer science, psychology, and cognitive science.²⁶

ARTIFICIAL INTELLIGENCE (AI)

A collection of different technologies that seek to emulate and implement aspects or features of human (or natural) intelligence in machines. Current major subdivisions of AI are computer vision, language processing and robotics.

AUTHENTICITY

The degree to which a person's actions are congruent with their values and desires.²⁷

BIAS

A disproportionate weight in favour of or against an idea or thing, usually in a way that is closed-minded, prejudicial, or unfair.²⁸

BRAIN

The central organ of the human nervous system (Ienca, 2021a).

BRAIN ACTIVITY

The exchange of electrochemical signals between neurons (brain cells), which is commonly measured indirectly by different kinds of brain imaging (see below).

BRAIN FUNCTION

The function of neuronal circuits in the brain (Ienca, 2021a).

26 <https://www.bbvaopenmind.com/en/technology/digital-world/what-is-affective-computing/>

27 [https://en.wikipedia.org/wiki/Authenticity_\(philosophy\)](https://en.wikipedia.org/wiki/Authenticity_(philosophy))

28 <https://en.wikipedia.org/wiki/Bias>

BRAIN COMPUTER INTERFACE (BCI) (also referred to as brain machine interface)

A computer-based system that acquires brain signals, analyses them, and translates them into commands that are relayed to an output device to carry out a desired action. In principle, any type of brain signal could be used to control a BCI system. (Shih *et al*, 2012)

BRAIN DATA (also referred to as neural data)

Data that are recorded directly or indirectly from an individual's brain, such as with brain imaging, intracranial recordings, or a brain computer interface.

BRAIN DISORDERS

Psychological or neurological disorders that impair a person's ability to function across cognitive, emotional, sensory and/or motor domains.

BRAIN IMAGING (also referred to as neuroimaging)

Techniques that employ an interaction between brain tissue and various forms of energy (e.g., electromagnetic or particle radiation), rather than physical incision, to capture positional data about the structure and function of the brain.²⁹ Types of brain imaging mentioned in this report include computerized tomography scanning, (functional) magnetic resonance imaging, electroencephalography, magnetoencephalography, cranial ultrasound, positron emission tomography and functional near-infrared spectroscopy

BRAIN STIMULATION (also referred to as neurostimulation)

Activating or inhibiting the brain directly with electricity. Electricity can be applied directly by electrodes implanted in the brain, or noninvasively through electrodes placed on the scalp. The electricity can also be induced by using magnetic fields applied to the head.³⁰

COMPUTATIONAL NEUROSCIENCE

Field of study in which mathematical tools and theories are used to investigate brain function. It can also incorporate diverse approaches from electrical engineering, computer science and physics in order to understand how the nervous system processes information.³¹

CONSCIOUSNESS

The state of being aware of and responsive to one's surroundings.³²

DEEP BRAIN STIMULATION

An invasive surgical procedure in which electrodes are implanted into certain brain areas. These electrodes, or leads, generate electrical impulses that control abnormal brain activity. The electrical impulses can also adjust for the chemical imbalances within the brain that cause various conditions. Stimulation of brain areas is controlled by a programmable generator that is placed under the skin in the upper chest.³³

29 <https://www.sciencedirect.com/science/article/pii/B9780128093245002741>

30 <https://www.nimh.nih.gov/health/topics/brain-stimulation-therapies/brain-stimulation-therapies>

31 <https://www.nature.com/subjects/computational-neuroscience>

32 <https://languages.oup.com/google-dictionary-en/>

33 <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Deep-Brain-Stimulation>

DIGITAL EXHAUST

All the information or 'consumer' data a person creates as they interact with websites and services. Digital exhaust contains highly sensitive personal information that can identify individuals and reveal their private activities.³⁴

DIGITAL PHENOTYPING

The moment-by-moment quantification of the individual-level human phenotype in situ using data from personal digital devices (Torous *et al*, 2016). The data that build a person's digital phenotype can be divided into two subgroups: active data and passive data, where the former refers to data that requires active input from the users to be generated, whereas passive data, such as sensor data and phone usage patterns, are collected without requiring any active participation from the user.³⁵

DIGNITY

The state or quality of being worthy of honour or respect.³⁶

DISCRIMINATION

The unjust or prejudicial treatment of different categories of people, especially on the grounds of race, age, sex, or disability³⁷– or in the context of neurotechnology, brain function.

DIRECT-TO-CONSUMER (DTC) (also referred to as business-to-consumer, or BTC)

When companies sell products directly to consumers, bypassing third-party retailers, wholesalers, or other middlemen.³⁸

EQUITY

Providing people with what they need, in order to make things fair. Unlike equality, equity means giving more to those who need it, proportionate to their circumstances, to ensure that everyone has the same opportunities.³⁹

EXISTENTIALISM

A form of philosophical inquiry that explores the problem of human existence and centres on the experiences of thinking, feeling and acting.⁴⁰

MENTAL ILLNESS (also referred to as psychiatric disorders)

A general term that refers to a group of illnesses, in the same way that heart disease refers to a group of illnesses and disorders affecting the heart. A mental illness is a health problem that significantly affects how a person feels, thinks, behaves, and interacts with other people.⁴¹

34 <https://mysudo.com/2020/08/what-is-digital-exhaust-and-why-does-it-matter/>

35 https://en.wikipedia.org/wiki/Digital_phenotyping

36 <https://languages.oup.com/google-dictionary-en>

37 <https://languages.oup.com/google-dictionary-en>

38 <https://en.wikipedia.org/wiki/Direct-to-consumer>

39 <https://social-change.co.uk/blog/2019-03-29-equality-and-equity>

40 <https://en.wikipedia.org/wiki/Existentialism>

41 <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/mental-pubs-w-whatmen-toc-mental-pubs-w-whatmen-what>

MENTAL INTEGRITY

Mental Integrity is the individual's mastery of his mental states and his brain data so that, without his consent, no one can read, spread, or alter such states and data in order to condition the individual in any way. (Lavazza, 2018, ref 26).

MENTAL PRIVACY

A right that explicitly protects individuals against the unconsented intrusion by third parties into their mental information (be it inferred from their neural data or from proxy data indicative of neurological, cognitive, and/or affective information) as well as against the unauthorized collection of those data. (Ilenca and Andorno, 2017)

MONISM

An approach to the mind-body problem that the mind and body are fundamentally one; in other words, there is only one unifying reality in substance or essence, in terms of which everything can be explained.⁴²

NATURALISM

The idea or belief that only natural laws and forces (as opposed to supernatural or spiritual ones) operate in the universe. All events, therefore, find their adequate explanation within nature itself.⁴³

NEURODEVICES (also referred to as neurological devices)

Devices that can be used to help restore hearing and sight or provide increased function for those with limb loss for congenital limb differences. Examples of neurodevices include neurodiagnostics, neurointerventional and neurostimulation devices.⁴⁴

NEUROGAMING

Emerging form of gaming where players interact with the game using a brain-computer interface (such as EEG), without the need for traditional controllers.⁴⁵

NEUROMARKETING

The measurement of physiological and neural signals to gain insight into customers' motivations, preferences, and decisions, which can help inform creative advertising, product development, pricing, and other marketing areas.⁴⁶

NEUROPROSTHETICS

Devices that can substitute for motor, sensory, or cognitive functions that have been impaired as a result of nervous system disorders (Kansaku, 2021).

NEURORIGHTS

Ethical, legal, social or natural principles of freedom or entitlement related to a person's cerebral and mental domain. (Ilenca, 2021a)

42 https://en.wikipedia.org/wiki/Mind%E2%80%93body_problem

43 [https://en.wikipedia.org/wiki/Naturalism_\(philosophy\)](https://en.wikipedia.org/wiki/Naturalism_(philosophy))

44 <https://www.fda.gov/medical-devices/products-and-medical-procedures/neurological-devices>

45 <https://en.wikipedia.org/wiki/Neurogaming>

46 <https://hbr.org/2019/01/neuromarketing-what-you-need-to-know>

NEUROTECHNOLOGY

The broad and heterogenous spectrum of methods, systems and instruments that establish a connection pathway to the human brain through which neural activity can be recorded and/or altered. (Ienca, 2021a)

NOOTROPICS

Types of drug often referred to as ‘cognitive enhancers’ that some people use in an attempt to improve memory, increase mental alertness and concentration as well as boost energy levels and wakefulness. Some nootropics are pharmaceutical drugs designed to treat conditions such as sleepiness or narcolepsy, and to improve attention and focus in people with attention disorders. However, some healthy people use these drugs in an attempt to improve their cognitive performance.⁴⁷

ONTOLOGICAL

Relating to the branch of metaphysics dealing with the nature of being.⁴⁸ A being is anything that can be said to be ‘being’ in the different senses of the word ‘being’. Aristotle described ontology as ‘the science of being as being’. More precisely, ontology is concerned with determining which categories of being are fundamental. Sartre: ‘Ontology seems to us to be able to be defined as the explanation of the structures of being of the existent taken as a totality and we will rather define metaphysics as the questioning of the existence of the existent’ (*L’être et le néant*).⁴⁹

PRIVACY

The ability of an individual or group to seclude themselves or information about themselves, and thereby express themselves selectively. When something is private to a person, it usually means that something is inherently special or sensitive to them.⁵⁰

PSYCHOLOGICAL CONTINUITY

People’s continuity of their mental life over time (e.g., continuity across non-synchronous mental states) (Ienca, 2021a).

REDUCTIVISM (also known as reductionism)

The practice of analysing and describing a complex phenomenon in terms of its simple or fundamental constituents, especially when this is said to provide a sufficient explanation.⁵¹

47 <https://adf.org.au/drug-facts/cognitive-enhancers/>

48 <https://languages.oup.com/google-dictionary-en/>

49 <https://la-philosophie.com/ontologie>

50 <https://en.wikipedia.org/wiki/Privacy>

51 <https://languages.oup.com/google-dictionary-en/>

ANNEX

Description of a Brain Computer Interface (BCI)⁵²

A BCI is most often a closed-loop system, including six main steps (Lotte, 2012):

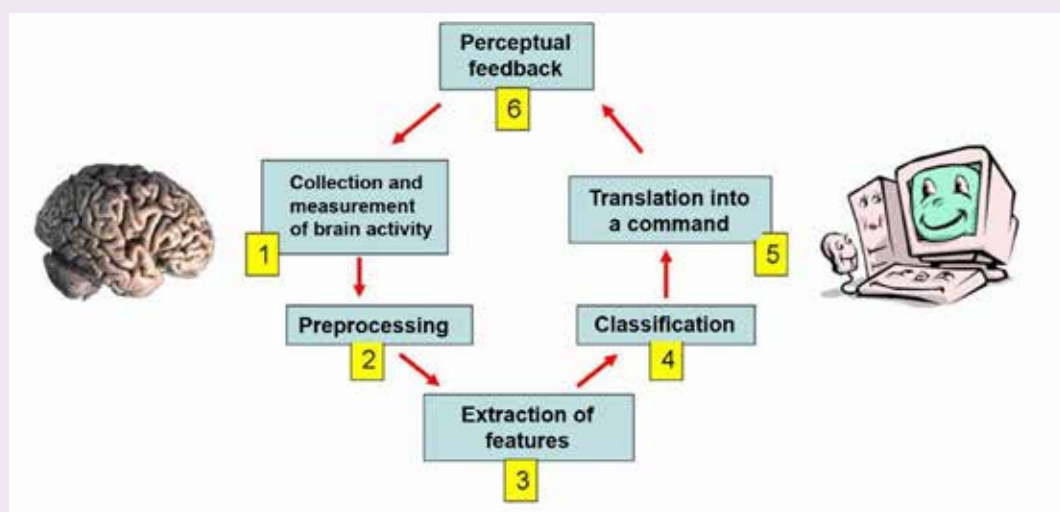


Figure 1: Example of a brain-machine interface (Huggins et al, 2009)

1. **Collection and measurement of brain activity.** The recording methods can be invasive or not. Invasive recordings use different types of electrode grids directly implanted in the cortical areas of interest (areas with motor, visual, auditory functions, etc.). The electrodes are in contact with the neurons and capture the action potentials they emit. Non-invasive recording methods, by their organization, underlie the codes forming the central messages (intention, ideas, etc.). Even if these methods operate as close as possible to the central

signalling, they have many drawbacks: displacement and loss of neuronal contact, gliosis, infections.

Among the non-invasive methods, we should mention neuroimaging techniques (fMRI, MEG, fNIRS), but EEG remains the most widely used method; it measures, through electrodes, the micro-currents present on the surface of the scalp. The electrocorticogram (EcoG) is an EEG performed in direct contact with the cerebral cortex, it is partially invasive.

2. **Preprocessing.** Spatial and temporal filters are used to eliminate parasitic muscular and ocular activities.
3. **Extraction of features.** This involves extracting from a large number of signals, characteristics (or patterns) concerning a given power in a frequency band. Thus, imagining a movement triggers activity in the motor areas, but the characteristics (or patterns) of the imaginary motor activity are of lower intensity than those of the real motor activity.
4. **Classification.** This step consists in assigning, thanks to an algorithm and a threshold value, a class to the vector of features that represents the type of mental task performed by the user of the BCI.
5. **Translation into a command.** The information is translated into a command according to the desired application. The command is given through a wired or wireless transceiver system.
6. **Perceptual feedback.** This corresponds to the closing of the feedback loop allowing the subject to learn to control their brain activity; without this feedback they are not able to do so. This is the basis of the neurofeedback principle.

Asynchronous and synchronous BCI

In the use of an **asynchronous BCI**, the subject interacts with the system when they decide to do so by voluntarily modifying their brain activity (EEG). The control signals are continuous and allow a progressive control such as a cursor. Several signals are used:

1. **Slow Cortical Potential Shifts (SCPS).** These are progressive variations of the average cortical potential (1 to 2 Hz for a few seconds), they are linked to mental states (availability...). Most subjects learn to control, by feedback, this potential and to provoke a positive or negative variation which is then transformed into a command by the ICM;
2. **Sensorimotor oscillatory activity.** This is recorded in the area of the motor areas and is modified during motor activity and also when the subject imagines a movement. The energy of these signals is in the frequency bands (8-15 Hz) and (15-25 Hz). The subject learns, by feedback, to control the variations of these rhythms in the case of imagined movements in order to drive a MCI.

In a **synchronous BCI**, it is not the spontaneous activity of the brain that is recorded but instead, the brain's response to a stimulus. The latter is detected in the EEG and transformed into a command. There are two main types of brain responses:

1. **Low-level visual evoked potentials (SSVERs: Steady State Visual Evoked Responses).** They appear in the primary visual cortex after a visual stimulus. These potentials occur with an increase in the amplitude of the EEG signal in the frequency band corresponding to that of the stimulus. Subjects learn to control the amplitude of the SSVER through feedback and use it to interact with the BCI as in the game 'Mind Shooter';
2. **Event Related Potentials (ERPs).** ERPs are EEG signals of short duration generated by a cerebral response to external stimuli (visual, auditory, tactile). One of the most commonly used ERPs is the P300 ERP which appears 300 ms after the stimulus and is related to a cognitive task. From then on, the detection of the P300 ERP is processed by the BCI to generate binary commands.

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ETHICAL ISSUES OF NEUROTECHNOLOGY

Sitting at the convergence point of neuroscience, engineering, data science, information and communication technology and artificial intelligence, neurotechnology raises unique ethical concerns.

The Report of the International Bioethics Committee of UNESCO on the Ethical Issues of Neurotechnology reveals the multifaceted impacts of advancements in technologies that “read” and “write” brain activity. Through investigating the intersection between neurotechnology, ethics and human rights, it identifies fundamental human characteristics and associated human rights that might be challenged by the development of this technology.

The Report puts forth recommendations to stakeholders at various levels, calling upon UNESCO, Member States, the research community, the industry, the media and the general public to take various actions to address the identified challenges and guarantee neuro-rights.



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