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PRELIMINARY DRAFT REPORT OF THE IBC ON ETHICAL ISSUES OF NEUROTECHNOLOGY

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 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 virtual working group meetings in May and September 2020.

This document contains the preliminary draft report prepared by the IBC Working Group for discussion by the Committee during its extraordinary session in February 2021. A synopsis of the preliminary draft report was also presented and discussed during the 27th (Ordinary) Session of the IBC in December 2020, which was held virtually with a condensed agenda. As it stands, this preliminary draft report does not necessarily represent the final opinion of the IBC and is subject to further discussions within the Committee in 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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I. INTRODUCTION

1. Brain activity is the basis of cognitive, affective or other brain states. Brain activity means human life since human 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 the brain to notions of human identity, freedom of thought, autonomy, privacy, and human flourishing makes of paramount importance ethical, legal, and societal impact of recording ('reading') and/or modulating ('writing') brain activity through various devices and procedures collectively named neurotechnology[1]. This report has been undertaken considering 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 in 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 anatomo-pathological method initiated by Laennec[2] allowed to link clinical findings to postmortem 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, led to the development of valuable drugs to combat a wide variety of neurological diseases, including the hitherto untreatable psychiatric disorders.

4. Even if nerves electrical properties were already reported by Luigi Galvani, Guillaume Duchenne de Boulogne, Herman Von Helmholtz or Charles Sherington to name just a few, birth of neurotechnology may be dated with the demonstration by Hans Berger in 1929 that it was possible to record changes of electrical potential in the human brain with electroencephalography device that 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 imaging techniques would be introduced in the latter part of the 20th century - 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 certain 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

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[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" Traité d'auscultation mediate 1819.

of animals or human beings. These include: (i) technical and computational tools that measure and analyze 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 with 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 the human brain activity and/or direct influence/modification of brain activity but can also be seen on a larger scale as any device and/or application (apps, AI, big data, etc.) able to derive knowledge on 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 consumer directed neurotechnology (DTC, neurogaming…).

9. Brain disorders, including neurological disorders and mental illness, represent a major and growing burden worldwide (one third of health expenses in developed countries (DiLuca and Olesen, 2014) and a growing burden in LMICs (Feigin et al., 2020)). 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 understanding of human brain function and unlocking the pathological conundrums of several treatment-resistant neurological and psychiatric disorders is a major priority.

10. Investment in brain research has become extremely important, with a growing number of large-scale programs aimed at developing technologies to intervene on the brain[3]. In 2013, the United States launched the Brain Initiative whereas the European Union launched the Human Brain Project. Japan, Korea, Australia, China and Canada also developed large programs on ‘cracking the brain’s code’, both to better understand its structure and mental processes, and to develop new technologies to, among other things, control robots, autonomous systems, 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, the consumer market). Consumer neurotechnology, digital phenotyping[5] affective computing, neurogaming[6] and neuromarketing[7]

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[3] https://www.internationalbraininitiative.org/

[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). We define in this report neural data as data relating to the functioning or structure of the human nervous system of an identified or identifiable individual that includes unique information about their physiology, health, or mental states.

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

[7] Neuromarketing is the study of the cerebral mechanisms likely to intervene in consumer behaviour.

are some of the domains where this 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 their medical use or in the field of scientific research even though some countries actually develop new legal instruments. Of note, the OECD Council adopted on 11 December 2019, the OECD Recommendation on Responsible Innovation in Neurotechnology, aiming to guide governments and innovators to anticipate and address the ethical, legal and social challenges raised by novel neurotechnologies while promoting innovation in the field (OECD, 2019) that presently remain non-binding principles.

13. As these technologies can be used to enhance 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 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 sits at the convergence 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 previous *Report of the IBC on Consent* (UNESCO, 2008) and *Report of the IBC on Big Data and Health* (UNESCO, 2017a)).

15. The *Universal Declaration on Bioethics and Human Rights* (UNESCO, 2005) offers a general framework to analyze the legal and ethical aspects and implications of neurotechnology, specially 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).

16. This report will investigate the intersection between neurotechnology, ethics and human rights, and envisage for the adaptive interpretation of human rights in light of emerging technologies applied to human brain activities. More precisely, the scope of the report will embrace the numerous ethical and legal issues raised by reading and writing the brain to ask if the questions are so large and so novel that we consequently need a novel 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 if these rights challenged by neurotechnology are already enshrined in existing human rights, but need to be more explicitly respected.

II. SHORT OVERVIEW OF EXISTING NEUROTECHNOLOGY

II.1. Neuroimaging

17. **Neuroimaging** or **brain imaging** are the techniques to either directly or indirectly access the structure and function (reflected by electrical activity, oxygen and/or energy consumption) of the central nervous system. 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 scan** uses computer-processed combinations of many X-rays 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 electric activity of the brain. **Positron emission tomography** (**PET**) is an imaging technique that uses radioactive substances injected intravenously to visualize and measure 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 deoxyhemoglobin concentration and is a rapidly developing non-invasive technique to evaluate changes in cerebral blood flow to given regions of the cerebral cortex. Of note, people wearing (mobile) fNIRS can move around in a relatively unconstrained way due to its robustness to movement artefacts allowing to record their brain activity in real life conditions – nothing like MRI, MEG, PET or EEG in that regard.

18. **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

19. Neurotechnology and neurodevices can replace parts of the body (eg, robotic prostheses) or alter functions of the brain (eg, implanted deep brain stimulators - DBS), in order to improve people's health and well-being. Deep brain stimulation 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 integration of algorithms to adapt the stimulation to patient's activity and/or remote access through wireless devices.

20. Deep brain stimulation is approved to treat a number of conditions, such as Parkinson's disease, essential tremor, dystonia, epilepsy, obsessive-compulsive disorder. Deep brain stimulation is also being studied as a potential treatment for major depression (major), Traumatic

brain injury, Stroke recovery, addiction, chronic pain, cluster headache, dementia, Tourette syndrome, Huntington's disease, multiple sclerosis.

21. 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 their worsening by DBS have been reported.

II.3. Brain computer interface

22. **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. increasing mood in a depressed person or moving a prosthetic limb). This is 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.

23. 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, such as Ecocorticography (EcoG) technology. Noninvasive 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, that uses 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. Cochlear implants are another example of a device that has received strong ethical challenges from the deaf community (Hyde and Power, 2006).

24. 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 paralyzed 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 also applied for medical tasks, with prominent examples being convolutional neural networks (ConvNets) on EEG signal (Schirrmeister, 2017).

II.4. AI in neurosciences

25. **Artificial Intelligence** is a broad term that refers to the activity devoted to make machines ‘intelligent’, such as what is required for computer vision or ‘autonomous’ robots. While there is no single agreed-upon definition of AI, it is widely agreed that machines based on or which incorporate 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). To be able to perform such tasks, a device embedded with AI needs to be able to sense the environment and to collect data dynamically, to process it promptly and to 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 strictly linked to neuroscience and neurotechnology.

26. There are also 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).

27. 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** as 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).

28. 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).

29. The convergence in AI, microsystems engineering and big data methods, make **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 also create important ethical, legal, philosophical, social and political challenges.

30. 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 illness from patterns of activity or structural anomalies in brain scans. There are many ethical issues related: automatic diagnoses changing the model of patient doctor relationships, algorithm discrimination, incidental findings and privacy concerns, transparency and bias, among others.

II.5. Neurotechnology in medical and non-medical interventions

31. Obviously, neurotechnology is developed and used for health-related purposes and cognitive enhancement. But it is increasingly being applied in contexts outside the healthcare domain. For instance, the industry is incorporating neuroscience in the conception 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.

III. NEUROTECHNOLOGY AND ETHICS

III.1. Neurotechnology and ethical principles

32. 'Neuroethics'[8] (Figueroa, 2016; Dubljević, 2017) deals with the 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

[8] The term Neuroethics is attributed to William Safire in early 2000 (Safire, 2002)

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 mainly at stakes (despite there are implicit consequences for the neuroscience of ethics).

33. Currently, neurotechnologies and the use of drugs (with implications on the **brain**) have **a high level of uncertainty**, about benefits and risks. Neurotechnologies have the potential to **affect bioethics**, both in theory and in **practice** and require reflections **on philosophical and ethical concepts**: human dignity, personal identity, autonomy, mental privacy, accessibility and social justice. It also raises questions related to the accessibility to such new technologies which is a common ethical concern on new technologies (justice and equity) common to other new technologies. Specific problems emerge in therapy and enhancement use contexts.

34. Examination/assessment of ethical issues raised by the use of neurotechnology should consider the context of their application. In example, brain implants will not raise the same questions when used to treat neurological disease such as Parkinson's disease or to treat mental health disorders. It has been reported a lack of discussion concerning core ethical issues (informed consent, risk, safety, and incidental findings) associated with either the conduct or results of MRI research on **mental health disorders** (Anderson et al., 2012). Issues will be different when neurotechnology is developed in the health sector or beyond (including gaming, marketing, education, etc.).

III.1.1. Cerebral/mental integrity and human dignity

35. Given the growing neurotechnological possibilities to modify the brain, and consequently the mind, also in an invasive and pervasive way, it is necessary to discuss the integrity of the brain and mind in the framework of the integrity of the human body

36. Ienca and Andorno (2017) recognise 'mental integrity' as a value, in front of the neurotechnological possibility to provoke "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.

37. In this perspective integrity of the body, and brain/mind as part of the body, is based on the dignity of every human being. Having dignity means having a value to be recognised, respected and protected from arbitrary alteration, modification, manipulation, which violates it and causes harm to the subject (who becomes an object).

38. Human dignity is the fundamental value enshrined in the Human Rights doctrine and in the *Universal Declaration of Bioethics and Human Rights* of UNESCO. But the concept of dignity, because of philosophical pluralism, has different meanings, with different ethical implications. At least three meanings need to be mentioned in the context of the advancement of neurosciences and neurotechnology: the ontological dignity, which refers to the very being and nature of every human being as the permanent possibility to increase or decrease their own natural/intrinsic capacities; the transcendental dignity (Kant), each person has a specific value because of the possibility of autonomy, for being an end for himself; an existential and extrinsic meaning, which identifies dignity on the way in which everyone acts in their existence. *[Note – Remarks by Marie-Geneviève: It's not right: in existentialism, it is not the way in which everyone acts in their existence that defines dignity but the real fact that everyone has to construct him/herself by every acts of his/her life. The dignity of human being is to do his/her best to decide of his/her life through every action. Of course, it could be easier for one person than for another but they possess all the same dignity defined as the will to construct his/her life by him/herself.]*

39. The ontological and transcendental perspectives on dignity include equality (every human being, because of their nature and possibility of autonomy, have dignity regardless of the absence

or weakness of manifestations of their functions). The existential and extrinsic view considers inequality as possible (people not able to exercise freedom, or in condition of fragility and low quality of life cannot have the same level of dignity; people with superior performances may be considered to have 'more' dignity) *[Note – See remarks by Marie-Geneviève above]*. According to the existential and extrinsic view dignity is not de facto possessed but has to be gained by the choices and the behaviour of each person at every time, that is why dignity should be different from one person to the other. The different concepts of dignity have relevant implications on patients with mental illnesses, severe mental disorders, etc., and also to healthy persons using enhancement.

40. The IBC recognises the pluralistic debate on human dignity and emphasizes that the recognition of the dignity of every human being is linked with human rights, and includes the recognition of integrity of the body and equality. In this sense the integrity of brain/mind needs to be respected, considering any form of neurotechnological alteration, modification, manipulation a violation of the human dignity. Dignity depends from the presence or absence of an individual's ability to exercise their freedom, above all in libertarian view; or the quality of life, in utilitarian view; or the respect of the self-linked to the capacity to plan one's life in accordance with one's values.

III.1.2. Personal identity and psychological continuity

41. 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 conception 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 is variable according to philosophical conceptions.

42. Contemporary reflection on personal identity has mostly been built upon the thought of John Locke (Locke, 1674), whether to validate or criticize Locke's original ideas. As a 17th 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**[9]. The **criticisms** of this conception can be presented according to five major approaches.

43. 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, the identity of the person remains unchanged depending on whether or not he had such a desire, such a memory, etc. The third is the **narrative approach** which proposes 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 the recognition of this 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.

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[9] 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. On the ethical point of view, it means that A will be held responsible for the actions of B if A remembers these actions.

44. The different approaches to personal identity have different implications in discussions on neurotechnologies. The ethical aspects of neurotechnology with regard to personal identity concern the possibility to change personal identity and the condition to exercise autonomy and responsibility, and informed consent. The **notion of personal identity is different from the notion of body identity**. The body can change form (e.g. enlarge, as with development and/or weight gain), it can lose some parts (e.g. amputation) or gain some parts (e.g. an external protheses) without ceasing to be experienced by the person as their own body, and to be perceived by others as the body of the same person.

45. **Continuity and distinctiveness of the self are bodily and ethically embedded.** The way in which the self is bodily embedded is double: 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 himself when he acts according to his desires and preferences or that if a person acts independently, responsibly, and sincerely, he acts authentically.

46. To understand if neurotechnology pose a threat, and 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.

47. **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. In itself, the reconstruction of this identity is not to blame; it is what happens when one integrates past experiences to repeat them or to 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.

48. Deep Brain Stimulation (DBS) can pose a threat to an individual’s body-to-body unity as **their authentic self**. Indeed, if 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, and this, perhaps, without the patient's knowledge. Note that this possibility is not specific to the DBS but to any device implanted or linked in one way or another to a human being.

49. 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 disorder, which appear earlier in life, it is the behavior of the person, including their way of thinking and feeling, that is targeted. But even in this case, it is more precise changes in behavior more than a total change in the person that seem to be put forward by the patients. 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.

50. Furthermore, **DBS** may interfere with the natural process of decision-making, raising questions about the person self-governing, especially when these closed-loop systems increasingly use AI software that autonomously adapts their operation.

III.1.2.1. Neurotechnology and the developing brain: personal identity of Children and Adolescent

51. All the emerging issues related to personal identity and neurotechnologies raise the ethical need of **precaution** in front of the risks and uncertainties. Understanding the development of the brain and its relationship to other biological systems in the prenatal, perinatal, early childhood and adolescent periods, it is becoming increasingly clear that historic debates about the ascendency of genetics (nature) or that of the environment (nurture) have been superseded by an as yet-evolving understanding of the complex interaction between nature and nurture that shapes the growing child: emotionally, socially and behaviorally.

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 lifespan.

53. Neurotechnology have the potential to transform children and adolescents' plastic, still developing brain in myriad of ways that will shape their future identity with long-lasting, if not permanent, effects. Neurodevices and BCIs embedded while an individual's is still undergoing significant neurodevelopment (thought to extend until at least 25 years of age) make it difficult to distinguish charter traits and behaviour which 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. The increasing neurotechnological possibilities of cognitive monitoring/surveillance and influence (even change) in forms of intrusive/manipulation or alteration of cognitive functions, brain/mental decoding, reading and (possibly) writing (also semantic) represent possible interferences with cognitive processes, and above all with free and competent decisions of the individuals. The debate, both at the experimental and philosophical levels, the existence/nonexistence of free will (starting from Libet's experiment[10]) is considered, in this context, not relevant for the bioethical discussion. It remains central the concept of autonomy. 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 it, we can consider that autonomous actions are analysed according to the following requirements: a) intentionality; b) awareness and c) absence of external influences that intend to control and determine one's action (Beauchamp and Childress, 2001). A person is autonomous when she/he is capable of exercising his/her autonomy in a free and informed way.

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[10] Libet invited the participants to move their right wrist and to report the precise moment when they had the impression that 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 attention was focused on a specific negative brain potential, namely the 'readiness potential', originated from a brain area involved in motor preparation, which is visible in the EEG signal as a wave that starts before any voluntary movement, while being absent or reduced before involuntary and automatic movements. (Libet et al., 1993)

55. Our actual increasing knowledge of, and research on, the human brain can lead us to question if human beings can take, effectively, 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, whether the decisions taken before the intervention remain after any changes, or not, and, if so, it is mandatory to reformulate the previously expressed declarations of will.

56. With the autonomy principle in mind, the approach, in the context of neurotechnologies, can take two different perspectives: the first, autonomy to consent with respect to the use of neurotechnology on the subject's body – as a participant in a research study, as a patient benefiting from a therapeutical application, or, as a consumer (of a medical or non-medical grade neurotechnology device). And the second, focused on the acquisition, data handling, use and sharing of neural data for different ends. (see legal section).

57. 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 intervening in the brain or manipulation of neural activity.

58. The natural evolution of someone's identity which occurs during the lifespan may be disrupted by brain damage or intervention. What may be called 'rehabilitation' of the brain may also contribute to significant changes of an individual's autonomy. Capacities may be restored, enhanced or disrupted.

III.1.3.1. Autonomy and informed consent

59. "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).

60. 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).

61. Informed consent takes, in the context of neurotechnologies, **different positions**, depending on the position assumed by the human being during his/her life: as a participant in a research study; as a patient who needs neurotechnology devices for treatment; as a consumer of neurotechnological devices for medical purposes; as a consumer of neurotechnological devices for non-medical use; as a person whose behaviour and decisions are influenced by neurotechnology.

62. It is **transversal** to different situations such as the possible changes on the decision-making competence, consent for research, privacy issues that will determine whether a person consents on research or, as a consumer, if he/she will acquire, or not, a neurodevice that introduces or records brain signals and may have direct and indirect influence on one's privacy and the use of data for broader purposes.

63. Ethical dilemmas in surrogate decision making are quite 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 decision, once they acquire the maturity and the legal right to consent for their own. Although it is expected that parents act in their children's best interest, requesting information of a predictive nature or

making decision on behalf of a child whose potential health condition will most likely occur in adulthood could be inconsistent with respect for his or her autonomy.

64. 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).

65. An individual has to 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 health-care professionals to convey to a patient or research participant this information in an intelligible language (UNESCO, 2008).

66. If, as it still occurs with neurotechnology, risks and benefits are still, in many occasions uncertain there may be doubts about the validity of informed consent because of the lack of the required information.

67. 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, 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).

68. On 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).

69. The fact of 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 comprehend. This introduces an unknown and perhaps unaccountable process between a person’s thoughts and the technology that is acting on their behalf (Drew, 2019).

III.1.4. Mental Privacy

70. As it has been explained in our previous *Report on Big Data and Health* (UNESCO, 2017a), the right to privacy is tightly linked to the right to freedom with its diverse legal and ethical aspects like freedom of speech, of association, of location, of movement and space, of beliefs, thoughts and feelings, and of behavior. Against this background, the IBC uses the term privacy in the sense of a right to respect for private life in relation to those areas of life that individuals want

to keep reserved for themselves or, at least, for some specific members of their families or relationships.

71. Neurotechnology may transmit brain data and digital data related to the brain activity of their users. Implanted neurodevices, such as those used in DBS, or even non-implanted 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.

72. 'Mind reading', especially in relation to unexpectedly found data or detection, based on the neuroimaging of psychological states unknown to the individual and for which they were not considered in the range of possibilities or risks of detection can have personal implications and very complex social issues. On the other hand, such data may be obtained without the knowledge, thus, without the consent of the individual affected or even the awareness that such information is being taken.

73. "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).

74. 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.

75. So, the question 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 one's brain. It has to be realized that the brain is what generates one's mind. This is the only data that gets to one's mental processes. If the assumption is "I am defined by my brain", then neural data may be considered the origin of the self and require a special definition and protection.

III.1.5. Accessibility and social justice

76. 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.

77. Since neurological and mental disorders are of higher incidence in population in poverty, it is foreseeable that the medical applications of neurotechnologies may be under increasing demand. In such circumstances strong regulations will be needed both to ensure that potential uses of neurotechnologies meet the highest bioengineering and medical standards as well as to prevent deceptive advertising and misuses of them. These regulations should be developed embracing the principles of responsible innovation, say, ensuring public accountability, inclusiveness, representativeness, enforceability and active character during the process of both designing and apply them (Daniels, 2008).

78. In contexts of deep social inequalities, neurotechnologies might potentially constitute a source of compensation to those patients that were suffering from neurological or mental disorders that could have been avoided if they had not had to live under poverty conditions. Conversely, limitations to access 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 accessing potentially scarce neurotech-therapies (because of their potential expensiveness for low income countries) be regulated by just distributive principles such as non-discrimination, highest potential medical benefit, social equity and transparency (WHO, 2016). In view of it, governments should begin to design and implement public policies focused in reducing brain health inequalities in the population –i.e. by ensuring high quality nutrition in early childhood as well as healthy and stimulant cognitive and emotional environments (Daniels, 2007; WHO, 2016).

79. The principle of non-discrimination with specific consideration of the particularly vulnerable is expressed in many previous reports of IBC including its *Report on the Principle of Individual Responsibility as related to Health* (UNESCO, 2019, paragraphs 38 and 42), *Report on Big Data and Health* (UNESCO, 2017a, paragraph 33), *Report on Social Responsibility and Health* (UNESCO, 2011, paragraphs 8-9, 40, 45 and 63), *Report on the Bioethical Response to the Situation of Refugees* (UNESCO, 2017b, paragraphs 61 and 70), *Report on the Principle of Non-discrimination and Non-stigmatization* (UNESCO, 2014, paragraphs 27 and 29), *Report on the Principle of the Sharing of Benefits* (UNESCO, 2015a, paragraphs 43, 44 and 112), and *Report on Updating Its Reflection on the Human Genome and Human Rights* (UNESCO, 2015b, paragraphs 3, 19 and 44).

80. Ensuring equitable access to neurotechnologies requires, amongst other things, effective governance of data sharing practices. Notably, cultural differences and a diversity of governance systems can complicate data sharing (Garden et al., 2019, p.7). These complications can be addressed through responsible translation of brain research from the lab to commercialization.

III.2. Enhancement purpose

81. **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 (eg, DBS in major depressions) question the authenticity and adequacy of his/her emotions related to a real-life context and can create problems for the user, in terms of how relate to other people across time (i.e., with the device activated vs. deactivated). Neurodevices incorporate data on the abnormal state that is intended to be corrected and data on the state of normality that is to be obtained, thus bringing into question the concept of normality in the functioning of the human brain or body. **Defining the concept of normality** is also essential in order to delimit the pre-existing condition from the neuro-enhancement which can be obtained by using neurotechnology.

82. Neuro-cognitive enhancement[11] refers to interventions designed to improve mental and emotional performance, considered 'normal', due to 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, neuro-imaging technologies to assess or alter brain function via neurofeedback, neurostimulation technologies to transiently alter brain function, such as transcranial magnetic stimulation or

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[11] Many Report and Opinions of Committees for bioethics on the topics. See U.S. President's Council on Bioethics. 2003. *Beyond Therapy: Biotechnology and the Pursuit of Human Improvemen*t; 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 *L'«amélioration» de l'humain par des substances pharmacologiques*, 2011; 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 Nr. 122; Italian National Bioethics Committee. 2014. "Neuroscience and pharmacological cognitive enhancement: bioethical aspects".

transcranial direct current stimulation applied over the cortex, or surgically embedding brain implants and employing a brain-computer interface. Neurocognitive enhancement deals with diverse methods of intervention, more or less invasive with regard to the body, with short- and long-term consequences, that despite differences share common goals of intervention, which can be identified with enhancing human capabilities, 'beyond' therapy.

83. **Moral neuro-enhancement** (Persson and Savulescu, 2012) consists in the use of drugs and technologies on healthy subjects to try to improve moral dispositions and capacities, such 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 with the activation of 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 conducts ('moral brain').

84. In **the medical field (therapy-derived),** the more sophisticated pharmaceuticals for the treatment of psychiatric and neurological syndromes and diseases (Alzheimer's, Parkinson's, dementia syndrome, attention deficit and hyperactivity, narcolepsy, autism, etc.) are used by 'healthy' individuals with the aim to increase to some extent memory, the capacity for concentration and learning, cognitive control, mood (i.e. the so-called smart drugs, lifestyle drugs or substances intended to alter lifestyle, cosmetic neurology, brain doping, the image of the body, that may be used offline for augmentation, extension of the vision.

85. 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, and the fact that they are not necessary and used without medical monitoring (in private settings[12]).

86. In **the military** (Italian National Committee for Bioethics, 2013)**.** Novel neurotechnology have potentially applications in treating physical and psychiatric injuries in the military setting, enhancing fighters' physical, cognitive, and emotional capacities, or by permitting neural remote control of weapon. Military applications of novel neurotechnology raise particular challenges because of the vulnerability of military in a hierarchical setting.

87. **The blurring between enhancement and therapy** comes out from the subjectivist view of health, considered 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. In the blurring the subjective perception of 'normality' plays a role. The case of cochlear implants for deaf children, the particular concept of 'normality' that underlies the promotion of therapeutic purposes of such implants has, in fact, been challenged by the same deaf community that refuses to consider their condition as being deficient

88. **Arguments in favor of enhancement** (Savulescu et al., 2011; Harris, 2010). Starting from the idea that enhancement and therapy are interchangeable, contiguous and equivalent, improvement is considered part of human development, consciously or unconsciously, with reference to any individual or social opportunity, whether natural or artificial (pharmaceutical or technological). It is considered a 'shortcut', as a self-determined choice by a free individual, in a free market, in the libertarian view. In the utilitarian perspective, enhancement is considered a

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[12] https://neuroscape.ucsf.edu/

stage of evolution to be replaced by ‘deliberate choice’ of the selection process, allowing to reach the same result rapidly and with much less effort. Although possible negative outcomes still remain unknown, halting progress in this direction would imply hampering or preventing the possibility of accelerating human evolution. It is the theory of ‘self-evolution’ and ‘enhancement evolution’ that shortens time required for evolutionary progress over millions of years, allowing man and humanity to attain and realize their full potential, in order to balance the effects of the natural lottery, in physical and social terms. This approach justifies a ‘duty to enhancement’ as a ‘duty of beneficence’, which is not only individual but also collective.

89. The **critical approach** (Kass, 2002; Fukuyama, 2006; Sandel, 2007) to enhancement underlines the threats to dignity as it is an attempt to overcome the limits of nature (i.e., not accepting them). The use of drugs or technologies for improvement purposes can cause serious harm, disproportionate compared to the expected benefits, which coincide with the fulfilment of subjective desires. Excessively risky interventions with regard to achievable benefits (deemed ineffective, costly and burdensome for patients), alongside irreversible and predictably inconclusive interventions, cannot be ethically, deontologically[13] justified, even if requested by patients. In this view enhancement is a ‘fraudulent misrepresentation’ to the detriment of others. In opposition to enhancement, achievement encompasses the dimension of acquirement, in the sense of development and realization of 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, society in general. This gives rise to an enhancement divide, a divide between the enhanced and unenhanced. This 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 re-proposes the ethical problem of eugenics, understood as the selection of the best: here on the basis of neurocognitive characteristics, jeopardizing “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).

90. **A special vulnerable category is the one of children.** Special attention altogether must be dedicated to children, because of their particular vulnerability, the possible long-term effects (still not fully known) of this type of nootropic on a brain still in development. Ethical concerns also must be addressed concerning the use of helmet electrode recordings to monitor children’s brainwaves in order to survey awareness and attention, by teacher and parents. This opens challenges to children, the mentally handicapped, persons who can easily be manipulated because of a specific weakness or dependence (e.g. drug addicts), captive institutionalized populations (prisoners, pupils, adolescents in supervised education, young people in homes, members of the armed forces, refugees) (UNESCO, 1995).

91. Paediatric enhancement is a rapidly developing topic, evaluating tools to shape children and ways to improve children’s capacities. These issues appear in a different light given new paths in technological development and changing demands and expectations regarding parenting

92. The dual-use of drugs and technologies, the fact that they may have clinical applications in therapeutic settings and may be applied in non-medical context with enhancement purposes, make the ethical justification a particularly sensitive and troublesome: a total ban on research and use of technology may hinder the development of a number of possible therapies a priori; at the same time, the discovery of certain technologies may encourage the use for enhancement

[13] Deontology is the duty entailed in the professional code of the researcher.

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.

93. Novel neurotechnology in military settings have potential applications in treating physical and psychiatric injuries caused by combat, as well as non-therapeutic uses, such as using BCIs to enhance fighters' effectiveness. 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 wellbeing of personnel with appropriate information.

94. There are, until now, no research study or proof of safety and efficacy of the use of pharmaceuticals or neurotechnology in off-label use in medical field (for enhancement purposes) or in non-medical filed. A number of small studies, most of them occasional with non-systematic analysis using neurotechnology report improvements in participants' performance in laboratory (for example memory or language skills, or in their mood). There is no statistical relevant sample, no repeated or repeatable test, no validate proofs. There is need for great care 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 such interventions on healthy subjects, given the absolute uncertainty and the possible high risks in the face of non-therapeutic and moreover implausible objectives. The obtaining of informed consent also represents a particularly delicate part of this and is an indispensable requirement to legitimate all 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 near to be applied both in the medical and non-medical field.

95. The risk also is, in a competitive society, a sort of medicalization and pathologization (searching for drugs and technologies to improve performances) not considering the social/environmental causes and diseases mongering, or market of pharmaceuticals. The justification of risk proportionality is a particularly sensitive issue[14]. These interventions are not necessary, but optional, selected by subjects experiencing non-disease conditions with the aim to feel 'better'. There emerges a profile of responsibility of the medical specialist who must ensure the appropriateness of the prescription and therefore prevent an 'improper' non-therapeutic use of these drugs.

96. Uses of non-invasive neurostimulation or BCIs either for 'enhancement' purposes or gaming do not pose generally serious health risks. But, the large number of people that use these applications and the lack of any clear associated health benefits mean that it is important to attend to several ethical concerns. In particular, to minimise 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. There is a need of observational research with children who are already using neurotechnology to address this and also that advice is issued to teachers and parents about the current evidence of the efficacy of neurofeedback as an educational enhancement tool.

97. It should also be considered that cognitive function can be improved in a more lasting manner through instruction, education and continuous training, a rich social life and from relationships, study, learning, continuous stimulation of hobbies and interests, and from leading a healthy lifestyle (in terms of nutrition, physical activity, etc.). It is a path that clearly requires a lot of time, but (perhaps) it is more respectful of the opportunities for growth and development of personal and relational identity.

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

98. “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 and about 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). Those supporting 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 is a debatable issue” (UNESCO, 2019)

III.3. Clinical ethics

99. Clinical ethics is a practical approach to making ethical decisions within a health care 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, 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 his or her concept of self, their human rights, and the function of their brain.

100. Ethical issues of neuro-technology within the clinical setting is 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 neuro-technology 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.

101. 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 (in all measures possible) by intervening when illness causes disorders of the brain.

102. Application of the principals involved in clinical ethics to neuro-technological developments therefore requires prudent intervention in disorders of the brain while strict 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.

103. Even in the context of clinical settings, special consideration should be given to vulnerable human beings and neurodevices. Procedures that are irreversible (surgical implants) or that have the capacity to produce imprints in children brains with durable effect 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 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 might not be considered as a something that needs to be ‘corrected’.

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

III.4. Research ethics in neurotechnology

105. Research in neurotechnology must comply with 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.

106. 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.

107. As the neuro-technologic 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 subjected to ethical considerations such as non-discrimination and privacy protection (for example, to prevent re-identification and unauthorized re-use), and ensuring benefit also accrue 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 be entitled to free medical treatment for such injury and to such financial or other assistance.

108. The exploring of neuro-technological developments for military purposes should be subjected to the ethical review requirements of research with human participants. Technological developments used for device control, deception detection and interrogation, as well as warfighter neuro-enhancement are examples of such research developments.

109. Ethical issues surrounding the commodification of ‘brain data’ will also need to be addressed, as will potential outcomes of neuro-technology such as affective computing, neuro-marketing, and human rights.

110. The problem of possible **misinterpretation** of data from neuro-imaging is an ethical concern, whereby images that suggest a non-standard or exceptional neurological anatomy could be interpreted as being informative and/or predictive. In regards to predictivity, 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**.

111. 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 result. Privacy of such information (and how it is being handled) may also be a concern for participants.

112. 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 to be informed of incidental findings should they so wish. Extra caution should therefore be taken in the formulation of the informed consent process. Further, the research project must ensure long-term follow-up especially in relation to invasive procedures.

113. The question of **the predictive value of brain images** and the possibility to diagnose certain dispositions in the brain (e.g. the likelihood to get a certain disease) is also of ethical concern. Of importance will be ascertaining the probability or certainty of such a disposition, since the possibilities of false positives (diagnosing a pathology that is not there) or the possibilities of false negatives (the failing to identify or communicate a possibly life-threatening condition) may have major consequences on patients.

114. 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 call for a special management of the information that has no immediate relevance in his or her health management. Such special care should be considered, for instance, when no treatment or preventive interactions are available.

115. In the novel field of neuro-technology there is a clear risk to an excessive reliance on ‘single-patient’ case reports. Here, there is a tendency of ‘selective reporting’, which may be highly problematic. This implies a possible over-reporting of positive results, but can also be the basis for duplication of efforts. 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. Introduction

116. The development of neuroscience and neurotechnology has made its presence felt in Law. Firstly, neurotechnology, as neuroscience in general does, opens new dilemmas for human rights and specifically for right to freedom of thoughts because the development of new technologies will make them able to access and read the individual thoughts, as we have explained before. It is thus challenging the basic assumptions of inalienable mental privacy. Secondly, because neuroscience also opens doubts about the proper legal concept of free will and, therefore, of legal responsibility and liability. If free will is not truth, it is a merely or not more than human creation without any scientific foundation, and it is not more than a human invention without any scientific support, the individual cannot be blamed for his or her actions because he or she is not criminally prosecutable. So, all our legal model based on coercion and punishment will be called into question. The basic question will be if personal responsibility can even exist, or whether there is a need for a justice system at all.

117. These two perspectives of the legal dilemmas derived from the evolution of neurotechnology are related to the distinction made by Adina L. Roskies in 2002 (in her article ‘Neuroethics for the New Millenium’), where she proposes a distinction between ethics for neuroscience and neuroscience of ethics. From a legal standpoint, the distinction could be between Law for Neurosciences, on other words, human rights for neuroscience and neuroscience of Law. In any case, the two concepts are also directly related because human rights could be one of or even the main limit to the intended transformation or disappearance of Law and the Justice system because the neuroscience improvements.

118. Neuroscience and Neurotechnology present themself 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

119. 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, which has traditionally been established to protect the autonomy of human subjects in health care 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).

120. Fast advances in neuroscience and the possibility to identify the neural correlates of decision-making also opens up the possibility of acquiring accurate information about people's competence to consent to medical clinical procedures and to medical research. The possibility to create 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?

121. 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. If we are strict in applying standards of decision-making capacity before accepting that someone is competent to consent, we would avoid most false positives, but at the cost of allowing many false negatives.

122. There is an international consensus that consent is generally required for medical interventions or for research on health[15], however, there are only rare occurrence of legally binding provisions regarding specific issues of informed consent on neurotechnologies or regarding specific matters such as neural data and privacy.

IV.2.1. (Consent to) Use of Brain Data

123. Brain data (also called neural data) includes data relating to brain structure and neural activity (see section on introduction). As information about the brain is intimate and private, its improper utilization may cause bias, discrimination, and breach of privacy, 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. Further, the brain generates the mood of a person, and so a person's position on a particular matter may be detected and monitored within the clinical

[15] The CIOMS *International Ethical Guidelines for Health-Related Research Involving Humans* (2016) distinctly states on its 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* that make clear statements on informed consent including for the protection of those not able to consent (vd. Articles 5, 6 and 7) (UNESCO, 2005); and others that are specifically focused on Neurotechnology such as the OCDE *Recommendation of the Council on Responsible Innovation in Neurotechnology* (2019) (OECD, 2019)

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, and so this could be an affront to privacy of thought (mental privacy).

124. 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 neuro-imaging 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 lead to neural data that involves not only conscious thoughts but in fact all brain activity, which may therefore 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. Predictive value of some neural data (for instance, brain imaging) calls for further precautions.

125. The *European Charter of Fundamental Rights*, at Article 3 – the Right to integrity of the person – states that everyone has the right to respect for his or her physical and mental integrity. This imposes the prohibition of 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.

126. First, informed consent is predicated on the ability of individuals to make free and competent decisions, but in the context of neuro-technology, the technology itself may interfere with the 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 and so the criterion of informed consent would not be met.

127. Secondly, there is a perception that information and understanding prior to consent is often unknowingly incomplete since users 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 start 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.

128. Third, there are questions raised as to whether the traditional informed consent instruments and guidelines are adequate to such uses of neurotechnology and if there is a need to provide more appropriate safeguards to protect confidential information (or, as it is called 'informational privacy' and 'brain privacy') given their exceptionally sensitive nature.

129. 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 capacity, self-identity, mood, mental process, etc. Similar questions were raised with genomics data.

130. Use of neural data outside the strict context of providing health care to an individual (for instance 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 indicate that 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.

131. Within the domain of brain data, there is the risk that the de-identified data may become identifiable subsequently, unless the means to protect mental privacy is specifically designed during and within the development of the technology itself.

132. In what concerns the consent to share data, alternative systems, such as the opting out system, are also suggested, with the consideration to treat neural data in the same way that organs and tissues are treated in some jurisdictions, for example for transplant purposes, where 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)

133. 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.

134. Finally, there is a need to review regulatory matters in other studies outside medical research, such as the case of neuromarketing companies which may run studies involving human subjects without a clear informed consent and an approval from an ethics committee.

135. More robust protective measures might be required in order to preserve the basic 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 to shape them (their perception as a human being) but could impact their future opportunities (employment, insurance, etc.).

136. Ethical issues surrounding the commodification of ‘brain data’ (Minielly et al., 2020) will needs to be addressed, as will potential outcomes of neuro-technology 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 and for how long (Yuste et al., 2017).

137. For non-medical applications, do the same rules of consent used on medical applications apply in the same way or a new set of rules need to be established is it needed to establish a new set of rules?

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

138. The right to freedom of thought and conscience have 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 article 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.

139. The right to freedom of thought appeared as a fundamental and human right at the beginning of the constitutional revolutions of XVIII and XIX centuries[16]. The right to freedom of

[16] The American 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 the all constitutional States have recognized the relevance of this right. In *Palko v Connecticut*, 1937, Justice Benjamin Cardozo wrote that some rights such as right to freedom of thought are so rooted in the traditions

thought is considered, for the Courts, the precondition of many fundamental rights such as freedom of ideology, freedom of religion. So, the need to protect it constitutes the way to guarantee the others. Freedom of thought has had two dimensions, the internal, where the individual has the right to adopt a personal position about life and to judge reality according to his or her personal convictions, and the external, based on *agere licere*, where the individual is able to express or act according to his or her ideas. As Mill describes it, that sphere includes: the inward 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 mean that it is at the top of the order of moral importance; but the sphere could be ‘first’ in the sense that it is where human freedom begins, for individuals or societies, or it might be paramount both with respect to its moral priority and its generative significance. Even Mill claims that the freedom to express and publish opinions is “practically inseparable” from freedom of thought, and “almost of as much importance as the liberty of thought itself.” And Rawls proposes that one should include freedom of thought 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 suggesting that freedom of thought has an essential role in specifying a just political procedure and maintaining 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.

140. Therefore, the right to freedom of thought is related not only to human dignity because human beings are expressive beings which need to conform 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 among freedom of thought, rule of law and democracy. Freedom of thought is not only included on lists of primary or cardinal rights and liberties, in notable philosophical treatments; it is often listed first.

141. Traditionally, the internal dimension was not controversial for Law, but it was proclaimed in all the Constitutions and International Conventions because it was considered a necessary precondition of the external one, as we said before. For Law, right to freedom of thought matters because its nature of precondition of liberty and freedom of expression and acting according to his or her thoughts. Even, the Courts have protected this internal dimension through the protection of the necessary means for the individual to develop his or her owns thoughts (for instance, access to publications, media, etc). Right to freedom of thought has appeared or has been invoked in front of the Court as a way to protect, not the thoughts itself, but the means to conform those thoughts.

142. However, the development of some technologies could change this paradigm when the machine will be able to go into the brain of the individual and, above all, his or her ideas and thoughts. Will be thought be limited by neurotechnology? Will individual be punished by his or her thoughts and not only by his or her actions?

143. Some authors have proposed the idea to develop a new cognitive freedom able to address these new conflicts. A sort of liberty of the mind using the terms of Charles Fried (2007, pp. 95-123, 160, 167). A new cognitive freedom in the sense of protecting also the internal dimension of

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and conscience of our people as to be ranked as fundamental 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 underlined that, until now, law has been guided by a strong common sense that assumes the freedom of the will as a real and work hypothesis in the solution of legal problems (Cardozo, 1937b).

thoughts. The position of the public powers won't be then to guarantee only the means to allow the individual conforming his or her thoughts, but also to guarantee the individual from any intromission in his or her thoughts. Will this be possible? What are the legal measures to guarantee this new perspective of the protection of the right to freedom of thought?

144. It is true that the last developments of the science of behavior is, in some sense, able to predict and also to control the individual. However, the impact of such development is over the actions or expressions of the individual, not over the thoughts. Through a WhatsApp message we are able to know about what the individual is expressing, but to find out what he or she is really thinking is not possible, unless we can go into his or her thoughts. We don't always act in strict correlation to our thoughts. We have always the guarantee that our thoughts are guaranteed from third parties. Even, we can consider that this is one of the most relevant perspective of our dignity and, above all, an important rule of social coexistence. Our dreams, opinions make us free considering that they are preserve from the control of the others and, because the social organization, we are able to think whatever we want but acting in a social correct form. Perhaps it is one or even the most difference between human beings and the rest of the animal species on Earth.

145. This new legal paradigm or challenge (developing new legal guarantees to protect freedom of thoughts from external interventions) is not in some sense new because it is quite similar to the paradigm of data protection which was developed mainly three decades ago. The improvement of new technologies and apps in the area of personal computers and the internet provoked the need of a new regulation of the new personal data. We could say that we don't need something pretty different, a new thoughts 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 guarantee confidentiality such as anonymity are called to play again a main role. A right to keep his or her thought and his or her personality away from any kind of intervention aimed at damaging individual liberty can be developed based on the principles and rules of data protection.

146. As Ienca and Andorno explain, 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 that genetic information is 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 from the interaction between genetics and human rights resulted 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 against discrimination – 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, similarly to 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.

IV.4. Freedom of thought vs. cognitive liberty. Are we talking about the same liberty?

147. As we said before, some authors consider that the current legal model developed for data protection and for biotechnology is very useful to address some of new issues and conflicts posed by neurotechnology from the human rights perspective but not enough because some of the issues and conflicts are new and different to the previous ones solved by Law. So, we should develop and include normatively some new rights and guarantees. Therefore, some of them have proposed, as a main initiative, to develop a new right to guarantee the individuals in the new context of the neurotechnology development: cognitive liberty. The first question that we should address about this proposal and the nature and meaning of cognitive liberty is if it is an adaptation to the traditional freedom of thought when the new context could transform something internal in something controllable by external tools. Are we talking about the same right in a different context or not? As Paolo Sommaggio et al. explains, cognitive liberty is a very complex concept due to its multi-dimensional features. Are we talking about a negative right, meaning that it imposes obligations on governments and others citizens to refrain from interfering with the rights bearer, or by contrast, about a positive formulation of cognitive liberty supporting that the existing neuro-technologies should be widely available to anyone who wants them?

148. If we analyze the different definitions of cognitive liberty, we will find that there is a sort of relationship between this right and enhancement in the sense that the new neurotechnology will be able to improve our mind power. So, considering this perspective we are talking about something directly related to the transhuman movement and its proposal about taking advantage of science evolution to develop a 'better' and more powerful human beings. Then, this new right will have positive meaning, not a mere liberty. This is the position of Christoph Bublitz, who supports that the right to cognitive liberty should be the central legal principle guiding the regulation of neurotechnogy, guaranteeing the right to alter one's mental states with the help of neurotools as well as to refuse to do so. 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. So, it is not a mere liberty related to dignity and privacy in the sense of let me thoughts alone, but something more related to a right to control the decision about our brain. This right includes not only a negative sphere but a positive one in the sense of giving the individual the faculty to accept the use of some neurotechnology tools to improve and, therefore, to enhance his or her brain.

149. In the Bublitz definition, there is something more than privacy, meaning that our thoughts must remain private until one decides to share them, as a legal guarantee to protect 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 neurotechnogy. And also something more than autonomy, related to the idea that every human being must be able to think independently and use the full spectrum of their mental faculties. For Bublitz, cognitive liberty includes also a third sphere, choice, proclaiming that the capabilities of the human mind should not be limited. Until one person directly damages others, governments should not prohibit cognitive enhancement or the realization of any other mental state.

150. On the other hand, there is the position of Ienca and Andorno (2017), for whom cognitive liberty should be understood as a negative right and not a positive one. For those authors, cognitive liberty is a prerequisite of all the rights focused on neuro aspects. Andrea Lavazza supports a similar position: cognitive freedom is a new form of freedom of thought that takes into account the power we now have, and increasingly we will have, to monitor and manipulate

cognitive function. As Lavazza explains, faced with the potential new threats to mental integrity due to 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 give access to the (more or less precise) prediction of the person's behavioral patterns through her neural connection and activation patterns. In fact, such information can be used for forms of prevention/discrimination based on the subject's hypothetical attitudes, or even to implement forms of forced re-education or compulsory moral bio-enhancement.

151. In any case, apart from the debate between transhumanist and bio-conservative, or between treatment, prevent or cure and enhancement, there can be also a sort of contradiction of those neuro-optimistic who are supporting cognitive liberty as a positive right in the sense of taking advantage of neurotechnology improvements and tools for enhancement: if this scientific development shows for the neuro-optimistic that there is not a real free will, how can we support such a positive right precisely based on free will?

IV.5. Neuroscience, neurotechnology and Law: towards a new legal system without free will

152. The development of neuroscience and neurotechnology is not only affecting the concept of freedom of thought as a human right, but also the legal and judicial system, based on the idea of free will. The only justification to criminalize and punish some actions of the individuals is his or her free will. Without assuming the concept of free will, Law cannot be understood and accepted.

153. It is true that Libet experiment has opened an interesting academic argument about the future of our legal system and, specifically, about our Criminal Law model based on free will.

154. Law is based on social conventions but not only on science. Science is important for Law because it provides elements to make 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 crimes investigation and for judging them.

155. The example of democracy can be a good one for our current debate. Our democratic systems are based on social conventions, not in scientific evidences. We are able to size intelligence but for the democratic systems the intelligence of the voters is not relevant, unless some cases of mental incapacity to make decisions. One vote for each voter without considering his or her intellectual preparation or its mental capacity from a neuroscientific perspective. All of us are equals in front of the ballot box and all of us are also equals in from of the legal systems for similar social and anthropological reasons. Our legal system is based on freedom and also on equality among human beings and it is difficult to imagine that this social convention will change even in the context of a huge improvement of neuroscience and neurotechnology.

156. A reasonable organization of human social life is not possible without the reciprocal recognition of freedom. The improve of knowledge about neurological processes is necessary to improve the functioning of Law and, especially, of criminal Law, but it is difficult to believe that it can replace it in our societies.

157. Therefore, we can address a huge development for neuroscience and neurotechnology without devaluating the role of Law and Justice. Neuroscience will provide Law with important new scientific evidences, as genetics did, mainly in the area of criminal competence, but free will as a social convention will be still there. Neuroscience will play and is currently playing a role in the area of the evaluation of mental capacity but not to dismiss free will as a legal foundation of 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 play also a role in civil law procedures, for example, in the assessment of an individual's capacity to contract, or of the severity of the plaintiff's pain in compensation claims. New and more reliable lie detection technologies based on our knowledge of the brain 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). The neuroscientifics as expert witnesses have an important role in front of the Court, but he or she won´t decide. The Judge will always make the decision.

158. The main question could be now if the human irrationality that we have accepted in many areas, such as Justice and democracy, is at its very 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 only in science is called to fail, as positivism did some decades ago. As 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". And as Kant said many centuries ago, a merely empirical doctrine of right (we can add "of Law") is a head that may be beautiful to look at, but unfortunately it has no brain.

159. Thinking that the brain / moral / law relationship is everything can lead us to forget that the measure of law, the very idea and essence of law, is human, whose nature results not only from 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 that would be made when we try 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 behavior 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 research involved automatic decisions which are not the decisions that we make in a moral or legal framework. The value of such research for Law is almost nothing.

161. Lawyer and physician John Ordronaux (who ran asylums in New York State) in 1874 articulated the slippery slope that worried many within both professional fields: Every vice, every crime is disease, nothing short.

162. As a way to conclude, it is important to remember that 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 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, H.T., 2009, p. 688). So, as mere tools we should not transform them in 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 to develop a world based on the relevance of human rights.

V. GOVERNANCE OF NEUROTECHNOLOGY

V.1. Responsible innovation

163. As described in the previous sections of this report, neurotechnology have the potential to deepen social inequities, to harm the privacy of individuals, to provide methods of manipulating the individuals (such as technologies of persuasion and personality altering technologies), but also to alter some basic human characteristics, such as privacy of mental life or individual agency.

164. The regulations in science and technology are late if they respond only to concrete realities generated by technologies already widely applied. For this reason, it is necessary **to anticipate the effects of implementing neurotechnology**, using scenarios in which society, science and future technologies are imagined and how they will interact (the so-called 'sociotechnical imaginaries'). The spectacular development of neurotechnology as well as new biotechnologies, nanotechnologies and ICTs make machines more and more humanoid, and people are becoming more connected to machines, indicating a pressing need for anticipatory governance.

165. 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, p.6). Notably, "neurohype and false promises can give rise to mistrust and unintended social effects" (Garden et al., 2016, p.646). Consequently, one of the relevant policy considerations that requires attention is the need to ensure "strong ''technological push'' of brain science towards addressing pressing societal needs", which can be achieved through public deliberation approaches across sectors (Garden et al., 2016, p.645).

166. 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 an agreement that the RRI framework is designed to enable stakeholders collectively discuss avenues for advancing societal goals through technology (Garden et al., 2016, p.643; Owen et al., 2013).

167. The three questions that should guide the RRI process as suggested by Garden et al. (2016, p.644) 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**.

168. In order to protect the dignity of people and humanity as a representation of the group to which we belong and which is distinguished by freedom, it is of capital importance to formulate a regulation for neurotechnology. Such regulation, may consist of a **personal oath** in which each inventor, producer, and seller of neurotechnology undertakes to use them and offer them for the benefit of users and in accordance with the respect of their human rights, to the formulation of neuro-rights that are stipulated in a UNESCO Universal Declaration of Neuroscientific and Neurotechnological Rights and a UNESCO Universal Convention that invites governments to establish a specific legal framework for such rights to be applied and / or sanctioned.

169. Specific mechanisms that can be used in this regard are free licensing to developing countries or fostering participation in patent pools to make the products affordable (Garden et al., 2019, p.35). These can be achieved through optimal use of suitable competition policies, which have been hailed for 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, p.75).

V.1.1. Engaging with the Public

170. Responsible innovation in neurotechnology must be a collaboration between science and society (Garden et al., 2019, p.7). In the process of developing neurotechnologies, it is essential to include the perspective (needs, concerns and experiences) of the people who will be affected by their use. This 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 inclusive by embracing public values in the innovation 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, p.7). This also eliminates unrealistic expectations that can erode public trust.

171. 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 use 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 the social stratification (the so-called 'technological divide').

V.1.2. Engaging with the Industry

172. Key players from the private sector such 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, etc. Consequently, the private sector should be involved in responsible development of technology during the early stages (Garden et al., 2019, p.6).

173. Obviously, it is expected from companies to be responsible for their neurotechnology products, and to make responsible claims about them (McCall et al., 2019). Neurotechnology development must be guided by standards, guides to good practices and ethical norms, resulting from the legal and ethical regulation of the field. However, neurotechnology raises such a unique set of societal and ethical issues that it requires proactive actions beyond regular product warranty.

174. Such good practices include having harmonized standards for neurotechnology innovation ensures 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, p.7). Standardising personal brain data collection, curation, and sharing are essential for driving new discovery and obtaining broader value from the data (Garden et al., 2019, p.7).

175. Developing gender-neutral products and ensure inclusive innovation are amongst elements of 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 perhaps an effective approach would be to engage the professionals involved in designing neurotechnologies (engineers, programmers, etc.) in subscribing to an oath of responsible innovation (bearing some similarities to the values upheld by the Hippocratic oath).

V.2. Public-private partnership

177. The potential of neurotechnology to affect many aspects of life and livelihood has attracted interest of both the public and private sectors, the former for the sake of public interest and the latter for commercial purposes. These different areas of interest are not mutually exclusive and public-private partnerships have been formed in various areas between governments, universities and commercial 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 which 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 memory loss, but also impact development of artificial intelligence. They are also important for learning, mass 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 public sector aims to gain knowledge on working of the brain and neural system and for the purpose of serving the public in neuromedicine, 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 into such research areas as devices for recording and modulation in the human central nervous system, next-generation human brain imaging and 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, and the China Brain Project. These projects largely aim to use information and communications technology, artificial intelligence technology and biomedical and related technologies in understanding and modifying brain functions and neurotechnology in general, and making use of the knowledge gained.

179. Public-private partnership can potentially yield benefits both to consumers and general public. From the knowledge gained from such partnerships, the consumers and general public can have 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 provide much needed investments 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, p.6). Additionally, such partnerships can help in tackling responsibility issues (Garden et al., 2019, p.35). 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. For example, how much should the private sector been entrusted with the task of collecting brain data of people? How can commercialization of brain data be regulated? What are the ethical implications of recording and modulating human thoughts and other brain processes? How far should the private sector be able to use data generated from public-private partnership? Good governance is also needed for public sector use of advances gained from public-private partnership. How far should governments be able to collect and collate brain data from the public, and for what purposes? Can governments allow public-private partnership to access such data and modulate public and individual brain processes? Although we are now well past 1984, the year when Big Brother could punish people for thought crimes in George Orwell's novel, these

and related questions form the core of ethical considerations in public-private partnership in neurotechnology.

180. Both private and public sector researchers need to be aware of, and deal with 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, ethical and legal concerns on research and products/procedures resulting from the partnership.

181. The public should also be aware of potential consequences of various public-private partnerships on neurotechnology, which may have potential impact on their lives and livelihood, ranging from use of the technology in monitoring and controlling behavior, 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 modes of work of researchers and institutions, including those involved in public-private partnerships, and should participate in debates on ethical aspects of neurotechnology, so as to ensure good governance and help answer the questions of ethical conduct in neurotechnology (Garden et al., 2019).

VI. RECOMMENDATIONS

(To be discussed)

"The physical and mental integrity allows people to fully enjoy their individual identity, and the right to act in a self-determined manner. No authority or individual may, by itself or through any technological mechanism, increase, decrease or disturb that individual integrity. Only the law may establish the requirements to limit this right, and the requirements that consent must fulfill in these cases."

Chile Constitution, 2020

1) It has also been suggested as an alternative to a new Convention, to add a specific chapter to the UN *Universal Declaration on Human Rights* to protect neurorights. At the same time, it is also the approval of a Code of Conduct into industry and academia would also be welcomed.

2) Among the rights that should be included, according to the opinion of scientists participating in the "Brain" project, are the following:

   a) Right to personal identity. It is possible that when connecting brains to computers, people's identity is diluted, because algorithms will help them make decisions and can blur the participation of the individual-self. To preserve such right, the selective, non-repetitive use of decision-inducing neurotechnology should be recommended.

   b) Right to free will. This neuro-right is very connected with the one of personal identity. When we have external tools that interfere with our decisions, the human capacity to decide their future can be questioned.

   c) Right to mental privacy. Due to neurotechnology interacting with the brain will have the capacity to gather all kinds of information about the subject in the most private field that we can imagine: his thoughts, it is essential to preserve the inviolability of the confidentiality of the 'neuro-data' generated by the human brain.

   d) Right to equitable access to technologies for the improvement or quantitative increase of capacities. Neurotechnogy can bring innumerable benefits for humans, but they can also bring an increase in the inequalities and privileges of a few who access these new human capabilities and the exclusion of those who do not have economic access, so it is necessary to make them accessible to the general population.

   e) Right to protection against bias and discrimination. The algorithms, working according to an average or standard, classify the population into groups and thereby multiply prejudices and biases. It is necessary, then, to detect these classifications and avoid them, before starting the offer of AI implements and neurotechnology.

   f) Right of individuals and the members of a group or institution such as schools, army, companies or any other to refuse the use neurotechnology and therefore not be excluded or devalued. Alternatives should be sought for them.

   g) Right to have access alternatives to the assets of contemporary society that are not neurotechnology and that offer the same effectiveness.

   h) Right to not be social bombarded by the neurotechnology marketing in order to promote a supposed human improvement.

i) Special considerations, (and perhaps specific guidelines) should be given to the use of neurotechnology and children, in order to preserve their future right to make autonomous decision, their privacy, as well as a respect for this defining period of life and the protection they need in order to develop as human beings.

GLOSSARY

(to be completed)

Artificial Intelligence
Authenticity

Bias
Brain
Brain activity
Brain computer interface
Brain data
Brain disorders
Brain imaging
Brain stimulation

Computational neuroscience
Computed tomography scan
Consciousness
Cranial ultrasound

Digital phenotyping
Dignity
Discrimination
DTC
EEG
Equity

Existential
Functional magnetic resonance imaging

Magnetic resonance imaging
Magnetoencephalography
Mental illness
Monistic

Naturalism
Neural data
Neurodevices
Neurodevices
Neuroprosthetics
Neurotechnogy

Ontological

Positron emission tomography
Privacy
Psychiatric disorders
Reductivism

Technology

BIBLIOGRAPHY

African Union (AU). 1981. *African Charter on Human and Peoples' Rights* ("Banjul Charter"). Banjul, African Commission on Human and People's Rights. Available at: https://au.int/en/treaties/african-charter-human-and-peoples-rights

Allhoff, F., Lin, P. and Steinberg, J. 2011. Ethics of human enhancement: an executive summary, *Science and engineering ethics*, Vol. 17, No. 2, pp. 201-212.

Anderson, J., Mizgalewicz, A. and Illes, J., 2012. Reviews of functional MRI: The ethical dimensions of methodological critique, *Plos one*, Vol. 7, No. 8, pp. e42836.

Andorno, R. 1998. *Bioética y dignidad de la persona*. Madrid, Tecnos.

Beauchamp, T.L. and Childress, J.F. 2001. *Principles of biomedical ethics*. Oxford, Oxford University Press.

Black, M.M., Walker, S.P., Fernald, L.C., Andersen, C.T., DiGirolamo, A.M., Lu, C., McCoy, D.C., Fink, G., Shawar, Y.R., Shiffman, J. and Devercelli, A.E. 2017. Early childhood development coming of age: science through the life course, *The Lancet*, Vol. 389, No. 10064, pp. 77-90.

Butler, J. 1736. *The Analogy of Religion*.

Cardozo, B. 1937a. *Palko V. Connecticut*. Washington DC, United States Supreme Court.

Cardozo, B. 1937b. *Steward Mach. Co. vs. Davis*. Washington DC, United States Supreme Court.

Changeux, J.P. 2004. *L'homme de verité*. Paris, Odile Jacob.

Changeux, J.P. 2004. *El hombre de verdad*. Fondo de Cultura Económica.

Changeux, J.P. and Ricoeur, P. 2000. *Ce qui nous fait penser. La nature et la règle*. Paris, Odile Jacob.

Chneiweiss, H. 2006. *Neurosciences et neuroéthique: des cerveaux libres et heureux*. Paris, Alvik Editions.

Churchland, P.M. 1988. *Matter and consciousness*. Cambridge, MIT press.

Cinel, C., Valeriani, D. and Poli, R. 2019. Neurotechnologies for human cognitive augmentation: current state of the art and future prospects. *Frontiers in human neuroscience*, *13*, p.13.

Commission nationale d'éthique dans le domaine de la médecine humaine (NEK-CNE). 2011. *L'«amélioration» de l'humain par des substances pharmacologiques*. Berne, NEK-CNE.

Council for International Organizations of Medical Sciences (CIOMS). 2016. *International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition.* Geneva, CIOMS. Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf.

Daniels, N. 2007. *Just health: meeting health needs fairly*. Cambridge, Cambridge University Press.

Danish Council of Ethics. 2011. *Medical enhancement*. Copenhagen, Danish Council of Ethics.

Davidson, D. 1968/69. Mental Events. In: *Experience and Theory*. Foster, L. and Swanson, J.W. 1970. Boston, University of Massachusetts Press.

DiLuca, M. and Olesen, J. 2014. The cost of brain diseases: a burden or a challenge? *Neuron*, Vol. 82, No. 6, pp. 1205-1208.

Drew, L. 2019. The ethics of brain-computer interfaces, *Nature*, Vol. 571, No. 7766, pp. S19-S19.

Dubljević, V., Jox, R.J. and Racine, E. 2017. Neuroethics: Neuroscience's Contributions to Bioethics, *Bioethics*, Vol. 31, No. 5, pp. 326-327.

Feigin, V.L., Vos, T., Nichols, E., Owolabi, M.O., Carroll, W.M., Dichgans, M., Deuschl, G., Parmar, P., Brainin, M. and Murray, C. 2020. The global burden of neurological disorders: translating evidence into policy, *The Lancet Neurology*, Vol. 19, No. 3, pp. 255-265.

Figueroa, G. 2016. Neuroethics: the pursuit of transforming medical ethics in scientific ethics, *Biological research*, Vol. 49, No. 1, pp. 1-7.

Finder, S.G. and Bliton, M.J. 2018. *Peer Review, Peer Education, and Modeling in the Practice of Clinical Ethics Consultation: The Zadeh Project*. Cham, Springer.

Fried, C. 2007. *Modern Liberty and the Limits of Government*. New York, W.W. Norton & Co.

Fukuyama, F. 2006. *The end of history and the last man*. New York, Free Press.

Garden, H. and Winickoff, D. 2018. Issues in neurotechnology governance, *OECD Science, Technology and Industry Working Papers (2018/11)*. Paris, OECD. Available at: https://dx.doi.org/10.1787/c3256cc6-en.

Garden, H., Bowman, D.M., Haesler, S. and Winickoff, D.E. 2016. Neurotechnology and society: Strengthening responsible innovation in brain science. *Neuron*, *92*(3), pp.642-646.

Garden, H., Winickoff, D.E., Frahm, N.M. and Pfotenhauer, S. 2019. Responsible Innovation in Neurotechnology Enterprises, *OECD Science, Technology and Industry Working Papers (2019/05)*. Paris, OECD. Available at: https://dx.doi.org/10.1787/9685e4fd-en

Garnett, A., Whiteley, L., Piwowar, H., Rasmussen, E. and Illes, J. 2011. Neuroethics and fMRI: mapping a fledgling relationship, *PloS one*, Vol. 6 No. 4, pp. e18537.

Gilbert, F., Cook, M., O'Brien, T. and Illes, J. 2019. Embodiment and estrangement: Results from a first-in-human "intelligent BCI" trial. *Science and engineering ethics*, *25*(1), pp.83-96.

Gracia, D. 1989. *Fundamentos de Bioética*. Eudema Universidad.

Gracia, D. and Jambrina, J.J.M. 2019. Lydia Feito Grande (2019). Neuroética: Cómo hace juicios morales nuestro cerebro. Madrid, Plaza y Valdés. *EIDON. Revista española de bioética*, (52), pp.130-133.

Habermas, J. 2008. *Between naturalism and religion: Philosophical essays*. Cambridge, Polity Press.

Harris, J. 2010. *Enhancing evolution: The ethical case for making better people*. Princeton, Princeton University Press.

Health Council of the Netherlands. 2003. *Human enhancement*. The Hague, Health Council of the Netherlands.

Hyde, M. and Power, D. 2006. Some ethical dimensions of cochlear implantation for deaf children and their families, *The Journal of Deaf Studies and Deaf Education*, Vol. 11, No. 1, pp. 102-111.

Ienca, M. and Andorno, R. 2017. Towards new human rights in the age of neuroscience and neurotechnology, *Life Sciences, Society and Policy*, Vol. 13, No. 5, https://doi.org/10.1186/s40504-017-0050-1.

Italian National Committee for Bioethics. 2010. *Neuroscience and Human Experimentation: Bioethical Problems*. Rome, Italian National Committee for Bioethics.

Italian National Committee for Bioethics. 2013. *Human Rights, Medical Ethics and Enhancement Technologies in the Military*. Rome, Italian National Committee for Bioethics.

Italian National Committee for Bioethics. 2014. *Neuroscience and pharmacological cognitive enhancement: bioethical aspects*. Rome, Italian National Committee for Bioethics.

Jarchum, I. 2019. The ethics of neurotechnology, *Nature biotechnology*, Vol. 37, No. 9, pp. 993-996.

Jonsen, A.R., Siegler, M. and Winslade, W.J. 1982. *Clinical ethics: a practical approach to ethical decisions in clinical medicine*. New York, McGraw-Hill.

Kandel, E.R., Schwartz, J.H. and Jessell, T.M. eds. 2000. *Principles of neural science*. New York, McGraw-Hill, Vol. 4, pp. 1227-1246.

Kant, I. 1788. *Kritik der praktischen Vernunft*. Riga, Johann Friedrich Hartknoch.

Kass, L. 2002. *Life, liberty and the defense of dignity: the challenge for bioethics*. New York, Encounter Books.

Klein, E., Brown, T., Sample, M., Truitt, A.R. and Goering, S. 2015. Engineering the brain: ethical issues and the introduction of neural devices. *Hastings Center Report*, *45*(6), pp.26-35.

Lavazza, A. and De Caro, M. 2010. Not so fast. On some bold neuroscientific claims concerning human agency, *Neuroethics*, Vol. 3, No. 1, pp. 23-41.

LeCun, Y., Bengio, Y. and Hinton, G. 2015. Deep learning, *Nature*, Vol. 521, No. 7553, pp. 436-444.

Levy, J. 2018. Transform everything into data to transform everything through data. In: Lasry, B. and Kobayashi, H. eds. *Human decision. Thoughts on AI.* Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000261563

Liao, L.D., Lin, C.T., McDowell, K., Wickenden, A.E., Gramann, K., Jung, T.P., Ko, L.W. and Chang, J.Y. 2012. Biosensor technologies for augmented brain–computer interfaces in the next decades. *Proceedings of the IEEE*, *100*(Special Centennial Issue), pp.1553-1566.

Libet, B. 1993. Unconscious cerebral initiative and the role of conscious will in voluntary action. In: Libet, B. ed. *Neurophysiology of consciousness*. Boston, Birkhäuser, pp. 269-306.

Libet, B., Gleason, C.A., Wright, E.W. and Pearl, D.K. 1993. Time of conscious intention to act in relation to onset of cerebral activity (readiness-potential). In: Libet, B. ed. *Neurophysiology of consciousness*. Boston, Birkhäuser, pp. 249-268.

Locke, J. 1674. *An essay concerning human understanding*.

McCall, I.C., Lau, C., Minielly, N. and Illes, J., 2019. Owning ethical innovation: Claims about commercial wearable brain technologies, *Neuron*, Vol. 102, No. 4, pp. 728-731.

Minielly, N., Hrincu, V. and Illes, J. 2020. Privacy Challenges to the Democratization of Brain Data, *Iscience*, pp. 101134.

Miraux, A. 2018. AI as a global change player. Three key challenges. In: Lasry, B. and Kobayashi, H. eds. *Human decision. Thoughts on AI.* Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000261563

National French Consultative Ethics Committee for Health and Life Sciences. 2012. *Ethical Issues arising out of Functional Neuroimaging*, Opinion Nr. 116. Paris, National French Consultative Ethics Committee.

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 Nr. 122. Paris, National French Consultative Ethics Committee.

Nelson, H.L. and Lindemann, H. 2001. *Damaged identities, narrative repair*. Cornell, Cornell University Press.

Nuffield Council on Bioethics. 2013. *Novel neurotechnologies: intervening in the brain*. London, Nuffield Council of Bioethics. Available at: https://www.nuffieldbioethics.org/wp-content/uploads/2013/06/Novel_neurotechnologies_report_PDF_web_0.pdf.

OECD. 2019. *Recommendation of the Council on Responsible Innovation in Neurotechnology.* Paris, OECD. Available at: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457.

Onnela, J.P. and Rauch, S.L. 2016. Harnessing smartphone-based digital phenotyping to enhance behavioral and mental health, *Neuropsychopharmacology*, Vol. 41, No. 7, pp. 1691-1696.

Owen, R., Bessant, J.R. and Heintz, M. eds. 2013. *Responsible innovation: managing the responsible emergence of science and innovation in society*. New Jersey, John Wiley & Sons.

Parfit, D. 1984. *Reasons and Persons*. Oxford, Oxford University Press.

Pedro, A.V. 2012. Coping with Brain Disorders using Neurotechnology. *The Malaysian Journal of Medical Sciences: Mjms*, *19*(1), pp.1-3.

Persson, I. and Savulescu, J. 2012. *Unfit for the future: the need for moral enhancement*. Oxford, Oxford University Press.

Plessner, H. 1927. *Die Stufen des Organischen*. Frankfurt am Main, Suhrkamp.

Popper, K.R. and Eccles, J.C. 1977. *The Self and Its Brain*. Berlin and Heidelberg, Springer-Verlag.

Raisamo, R., Rakkolainen, I., Majaranta, P., Salminen, K., Rantala, J. and Farooq, A. 2019. Human augmentation: Past, present and future. *International Journal of Human-Computer Studies*, *131*, pp.131-143.

Reid, T. 1785. *Essays on the intellectual powers of man*. Cambridge, Cambridge University Press.

Roskies, A.L. 2002. Neuroethics for the New Millenium, *Neuron*, Vol. 35, No. 1, pp. 21-23.

Roskies, A.L. 2010. How does neuroscience affect our conception of volition?, *Annual review of neuroscience*, Vol. 33, pp. 109-130.

Safire, W. 2002. Visions for a new field of neuroethics. In: Marcus, S.J. ed. *Neuroethics: mapping the field*. New York, Dana Foundation Press.

Sandel, M.J., 2007. *The case against perfection*. Cambridge, Harvard University Press.

Savage, N. 2019. How AI and neuroscience drive each other forwards, *Nature*, Vol. 571, No. 7766, pp. S15-S15.

Savulescu, J., Ter Meulen, R. and Kahane, G. eds. 2011. *Enhancing human capacities*. New York, John Wiley & Sons.

Schechtman, M. 1996. *The Constitution of Selves*. Cornell, Cornell University Press.

Schirrmeister, R.T., Springenberg, J.T., Fiederer, L.D.J., Glasstetter, M., Eggensperger, K., Tangermann, M., Hutter, F., Burgard, W. and Ball, T. 2017. Deep learning with convolutional neural networks for EEG decoding and visualization, *Human brain mapping*, Vol. 38, No. 11, pp. 5391-5420.

Schurger, A. and Uithol, S. 2015. Nowhere and everywhere: The causal origin of voluntary action, *Review of Philosophy and Psychology*, Vol. 6, No. 4, pp. 761-778.

Searle, J. 2006. *Freedom and neurobiology: Reflections on free will, language, and political power*. New York, Columbia University Press.

Shoemaker, S. 1996. *The first-person perspective and other essays*. Cambridge, Cambridge University Press.

Spenrath, M.A., Clarke, M.E. and Kutcher, S. 2011. The science of brain and biological development: Implications for mental health research, practice and policy, *Journal of the Canadian Academy of Child and Adolescent Psychiatry*, Vol. 20, No. 4, pp. 298.

Stilgoe, J., Lock, S.J. and Wilsdon, J. 2014. Why should we promote public engagement with science?, *Public understanding of science*, Vol. 23, No. 1, pp. 4-15.

Strand, R. and Kaiser, M. 2015. Report on ethical issues raised by emerging sciences and technologies. *Norway: Centre for the Study of the Sciences and the Humanities, University of Bergen*, Vol. 23.

Taylor, C. 1989. *Sources of the Self. The Making of the Modern Identity*. Cambridge, Harvard University Press.

U.S. President's Council on Bioethics. 2003. *Beyond Therapy: Biotechnology and the Pursuit of Human Improvemen*t. Washington DC, U.S. President's Council on Bioethics.

United Nations Educational, Scientific and Cultural Organization (UNESCO). 1995. *Ethics and Neurosciences.* Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000132339.

UNESCO. 1997. *Universal Declaration on the Human Genome and Human Rights*. Paris, UNESCO. Available at:
http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

UNESCO. 2003. *International Declaration on Human Genetic Data*. Paris, UNESCO. Available at:
http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

UNESCO. 2005. *Universal Declaration on Bioethics and Human Rights*. Paris, UNESCO. Available at:
http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

UNESCO. 2008. *Report of the International Bioethics Committee of UNESCO (IBC) on Consent.* Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000178124.

UNESCO. 2013. *Report of the IBC on the Principle of Respect for Human Vulnerability and Personal Integrity*. Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000219494.

UNESCO. 2014. *Report of the IBC on the Principle of Non-Discrimination and Non-Stigmatization.* Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000221196.

UNESCO. 2015a. *Report of the International Bioethics Committee of UNESCO (IBC) on the Principle of the Benefit Sharing.* Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000233230

UNESCO. 2015b. *Report of the International Bioethics Committee of UNESCO (IBC) on Updating Its Reflection on the Human Genome and Human Rights*. Paris, UNESCO. Available at: http://unesdoc.unesco.org/images/0023/002332/233258E.pdf

UNESCO. 2017a. *Report of the International Bioethics Committee of UNESCO (IBC) on Big Data and Health*. Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000248724.

UNESCO. 2017b. *Report of the International Bioethics Committee of UNESCO (IBC) on the Bioethical Response to the Situation of Refugees*. Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000248721

UNESCO. 2019. *Report of the International Bioethics Committee of UNESCO (IBC) on the Principle of Individual Responsibility as related to Health*. Paris, UNESCO. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000367824

United Nations (UN). 1945. *Charter of the United Nations*. New York, UN. Available at: https://www.un.org/en/charter-united-nations/

UN. 1948. *Universal Declaration of Human Rights*. New York, UN. Available at: http://www.un.org/en/universal-declaration-human-rights/

UN. 1965. *International Convention on the Elimination of All Forms of Racial Discrimination* (ICERD). New York, UN. Available at:
https://www.ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx

UN. 1966a. *International Covenant on Civil and Political Rights*. New York, UN. Available at: https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx

UN. 1966b. *International Covenant on Economic, Social and Cultural Rights.* New York, UN. Available at: https://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

Valenzuela, J.G. 2005. *Genoma humano y dignidad humana* (Vol. 59). Barcelona, Anthropos Editorial/National Autonomous University of Mexico.

Valenzuela, J.G. 2017. Bíos. El cuerpo del alma y el alma del cuerpo. Mexico City, Fondo de Cultura Económica/National Autonomous University of Mexico.

Van Est, R., Stemerding, D., Rerimassie, V., Schuijff, M., Timmer, J. and Brom, F. 2014. From Bio to NBIC convergence-From medical practice to daily life. *Report written for the Council of Europe, Committee on Bioethics, The Hague, Rathenau Instituut*.

Wiggins, D. 1980. *Sameness and Substance. Cambridge*. Cambridge, Harvard University Press.

Wiggins, D. 2001. *Sameness and substance renewed*. Cambridge, Cambridge University Press.

World Health Organization (WHO). 2016. *Promoting access, quality and innovation to save and improve lives: essential medicines and health products*. Geneva, WHO. Available at: https://apps.who.int/iris/bitstream/handle/10665/204469/WHO_EMP_2016.01_eng.pdf.

World Medical Association (WMA). 2013. *The Declaration of Helsinki*. Helsinki, the World Medical Association. Available at: https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki.

Yuste, R., Goering, S., Bi, G., Carmena, J.M., Carter, A., Fins, J.J., Friesen, P., Gallant, J., Huggins, J.E., Illes, J. and Kellmeyer, P. 2017. Four ethical priorities for neurotechnologies and AI, *Nature News*, Vol. 551, No. 7679, pp. 159.