Neurorights between ethical and legal implications

Neuroderechos entre implicaciones éticas y legales

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Abstract: Advances in neuroimaging and brain-machine interfacing (BMI) increasingly enable the large-scale collection and further processing of neural data as well as the modulation of neural processes. In parallel, progresses in artificial intelligence (AI), especially in machine learning, create new possibilities for decoding and analysing neural data for various purposes including health monitoring, screening for disease, cognitive enhancement, and device control. This contribution discusses some major ethical, technical, and regulatory issues associated with neural data analytics and delineates a roadmap for responsible innovation in this sector. Moreover, this paper review a variety of themes including mind reading, mental privacy, cybersecurity in commercial BMI, and issues of neurotechnology governance. Finally, a framework for responsible innovation and governance is presented.
Keywords: Neurorights, neurotechnology, rule of law.

Resumen: Los avances en neuroimagen e interfaz cerebro-máquina (BMI) permiten cada vez más la recopilación a gran escala y el procesamiento posterior de datos neuronales, así como la modulación de procesos neuronales. Paralelamente, los avances en inteligencia artificial (IA), especialmente en el aprendizaje automático, crean nuevas posibilidades para decodificar y analizar datos neuronales para diversos fines, incluidos el control de la salud, la detección de enfermedades, la mejora cognitiva y el control de dispositivos. Esta contribución analiza algunos de los principales problemas éticos, técnicos y regulatorios asociados con el análisis de datos neuronales y delinea una hoja de ruta para la innovación responsable en este sector. Además, este documento revisa una variedad de temas que incluyen la lectura de la mente, la privacidad mental, la ciberseguridad en el BMI comercial y los problemas de gobierno de la neurotecnología. Finalmente, se presenta un marco para la innovación y la gobernanza responsables.
Keywords: Neuroderechos, neurotecnología, estado de derecho.

I. Introduction

1. Advances in neurotechnology are fundamental to enhance our understanding of human brain and to improve the provision of neurorehabilitation and mental health services at global level. We are now entering a new development phase of neurotechnology characterized by greater and more systematic public funding on the one hand (e.g., the *BRAIN Initiative* in the US, the *Human Brain Project* funded by the EU and the *China Brain Project* initiated by the People's Republic of China), and diversified investments in the private sector, on the other (a couple of examples among many include neuro-focused companies such as *Kernel, Emotiv* and *Neuralink*). Another key element is the increasing availability of neurodevices beyond the clinical field. In the meantime, advances in the interaction between neuroscience and artificial intelligence (AI) are rapidly improving computational resources for neurodevices in both terms of data acquisition/analysis and output. While neurotechnology is becoming more and more socially pervasive and computationally powerful, several experts stressed the need for proper ethical groundwork and for a roadmap for both scientists and politicians[1].

II. Ethical implications

2. Within the broader neurotechnological spectrum, Brain-machine Interfacing (abbreviated as BMI) is of particular relevance from a social, legal and ethical point of view since its ability to establish a direct connection between human neural processes and artificial computation was described by sectorial experts as "qualitatively different"[2]. Therefore, BMI raises unprecedented ethical issues[3]. In parallel, the increasing use of big data models and advanced analytical techniques based on machine learning (ML) are boosting the epistemic power of existing neuroimaging procedures. Simultaneously, new scenarios of ethic-regulatory complexity open up.

3. In this regard, privacy plays a crucial role. Brain recordings allow to gather great amounts of information, for example by means of electroencephalography (EEG) or functional magnetic resonance imaging (fMRI). Such recordings may contain highly private information in encoded form on individuals from whom it is derived, including predictive features of their health status and their mental states. According to such informative potential, brain recording technologies have been frequently categorized as brain reading techniques[4], drawing a parallel between the possibility to decode information and mental states from neural data and functional interpretation of a written text by reading it. For example, several studies from the beginning of the third millennium have proved that it is possible to decode mental contents such as hidden intentions[5], hidden information[6], natural images[7], visual experiences[8] and the unconscious generation of free decisions[9] on the basis of individual neural data (previously collected by means of EEG, fMRI or other techniques). Some of these studies enjoyed a high degree of epistemological solidity so that they could be used to build predictive models. For instance, within two of the above-mentioned researches, it was used the fMRI technology to predict both stream of consciousness and decisions taken by examined subjects regarding motor preparation and, surprisingly, even abstract intentions. These studies raised reasonable clamour in the scientific community, being conscience, intentionality and free choice essential elements making up the so-called faculty of "free will", as it is traditionally intended from a theological-philosophical point of view.

[1] See, among the various bibliographical references: R. Yuste, S. Goering, G. Bi, J.M. Carmena, A. Carter, J.J. Fins, P. Friesen, J. Gallant, J.E. Huggins, J. Illes (2017), "Four ethical priorities for neurotechnologies and AI", *Nature News*, n° 551, 2017, p. 159; J. Clausen, E. Fetz, J. Donoghue, J. Ushiba, U. Spörhase, J. Chandler, N. Birbaumer, S.R. Soekadar, "Help, hope, and hype: Ethical dimensions of neuroprosthetics", *Science*, n° 356, 2017, pp. 1338-1339; M. Ienca, "Neuroprivacy, neurosecurity and brain-hacking: Emerging issues in neural engineering", *Bioethica Forum*, 2015, pp. 51-53.

[2] See R. Yuste, *et al.*, cit., p. 159.

[3] See J. Clausen, *et al.*, cit.

[4] See J.D. Haynes, "Brain reading: decoding mental states from brain activity in humans", *The Oxford Handbook of Neuroethics*, 2011, pp. 3-13.

[5] See J.D. Haynes, K. Sakai, G. Rees, S. Gilbert, C. Frith, R.E. Passingham, "Reading hidden intentions in the human brain", *Current Biology*, 2007, vol. 17, n. 4, pp. 323-328.

[6] See M. Bles, J.D. Haynes, "Detecting concealed information using brain-imaging technology", *Neurocase*, 2008, 14, 1, pp. 82-92.

[7] See K.N. Kay, T. Naselaris, Y. Benjamini, B. Yu, J.L. Gallant (2011), "Identifying natural images from human brain activity", *Nature*, n° 452, 7185, p. 352.

[8] See S. Nishimoto, A.T. Vu, T. Naselaris, Y. Benjamini, B. Yu, J.L. Gallant, "Recostructing visual experiences from brain activity evoked by natural movies", *Current Biology*, 2011, vol. 21, n° 19, pp. 1641-1646.

[9] See S. Bode, A.H. He, C.S. Soon, R. Trampel, R. Turner, J.D. Haynes (2011), "Tracking the unconscious generation of free decisions using ultra-high field fMRI", *PloS one*, 2011, vol. 6, n° 6, pp. 1-13.

4. Although the debate on decoding possibilities of both neural correlates of mental information and actual mental contents is still open[10], it is undeniable that quality and quantity of information gathered from neural recordings have been improving progressively and rapidly in the last years. This improvement process was affected not only by the upgrade at hardware level of existing machinery, but also, and most importantly, by upgrading analysis techniques. In this regard, artificial intelligence has played and keeps playing a key role. It is expected that decoding mental information will be increasingly easier in the nearest future thanks to coordinated progress in the fields of sensor technology, spatial resolution of acquired brain recordings and, lastly, machine learning techniques for pattern recognition and feature extraction[11].

5. There are three main privacy threats related to BMI: accidental disclosure of sensitive information, unauthorized access to collected data by third parties and data theft[12]. Such threats, as is well known, are common to other types of data as well, especially when it comes to data available within the digital ecosystem. However, it may be argued that privacy issues related to BMI are characterized by a greater level of complexity and ethical sensibility compared to other privacy threats conventionally associated to other digital technologies. This is because of the intimate connection between neural recordings, on the one hand, and mental states and predictive behaviour modelling, on the other. Indeed, neural recordings, unlike other electrophysiological measurements, allow to get a more direct and potentially detailed codification of the content of one's mental states, including private ones (i.e., not conveyed through verbal language, written text or observable behaviour). Such complexity reflects also at legal level; as a matter of fact, both privacy of personal information and mental states are legally relevant when defining legal entity and related responsibilities. Particularly, it should be provided a specific ethic and legal evaluation of the neural domain. In this respect, a valid proposal consists in establishing the right to "mental privacy"[13], intended as information domain of the human mind, prior to any possible form of externalisation by means of language, writing or observable behaviour.

6. The increasing use of machine learning techniques and, more generally, of artificial intelligence for the purpose of optimising the functioning of BMI also entails implications related to the notions of action and accountability. For example, Haselager suggested that, when control over BMI partially depends on an intelligent algorithmic component, it may be difficult to discern whether a certain behavioural output is in fact the result of an action performed by the user or not[14]. Thus, cognitive processes performed with the interference of BMIs open up to the so-called uncertainty principle, concerning first conceptualisation of an action (or intention), then its execution. This results in uncertainty in attributing accountability to the action's performer. Therefore, the uncertainty principle might challenge the concept of individual accountability, with obvious penal and insurance-related repercussions. Moreover, this could bring to the performer a sense of estrangement, whose ethical relevance is even greater in the case of vulnerable individuals such as neurological patients. By way of example, let us imagine a patient suffering from tetraplegia who makes use of a greatly enhanced BMI by means of intelligent components for information extraction, decoding and classification: how could it be determined which aspects of the patient's behaviour are attributable to the volition of the patient him or herself and which, instead, to the AI? Such a question becomes particularly controversial, as already mentioned, in circumstances in which accountability has legal relevance. Additionally, it is possible that BMI's intelligent components might influence subjective experience, i.e., the user's personal identity. Recently, this hypothesis preli-

[10] On this topic see the comprehensive analysis conducted by G. Mecacci, P. Haselager, "Identifying criteria for the evaluation of the implications of brain reading for Mental Privacy", *Science and engineering ethics*, 2017, n° 15, pp. 1-9.

[11] Among various scholars, such prediction was made by J. Clausen, *et al.*, cit.

[12] For a detailed analysis see M. Ienca, P. Haselager, "Hacking the brain: brain-computer interfacing technology and the ethics of neurosecurity", *Ethics and Information Technology*, 2016, vol. 18, n° 2, pp. 117-129.

[13] See M. Ienca, R. Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", *Life Sciences, Society and Policy*, 2017, vol. 13, n° 1, p. 5.

[14] See P. Haselager, "Did I do that? Brain-computer interfacing and the sense humans", *Minds and Machines*, 2013, vol. 23, n° 3, pp. 405-418.

minarily found empirical confirmation through a qualitative study concerning subjective experience of BMI patients-users[15]. However, it should be noted that AI may inhibit some individual aspects of personal identity, whereas BMI optimised through AI may, overall, significantly enhance users' performativity in a given environment. This specifically applies to patients with severe motor impairment. Therefore, it is difficult to determine in absolute terms whether intelligent BMIs can enhance users' performativity or not. Contrarily, it is necessary to pursue a case-by-case approach in order to determine, each time, under which circumstances, in which span of time and in relation to which cognitive-behavioural domains any variation (positive or negative) can be detected. While implementing this approach, it is important to gather both quantitative-objective evidence (e.g., mathematical measurements or behavioural observations) as well as qualitative-subjective data. The latter covers, in addition, data deriving from users' self-assessment, which is fundamental to have access to users' phenomenological dimension[16].

7. In parallel with BMI's increasing non-clinic use, another ethical challenge to face will soon be the so-called neuroenhancement. Clinic use of BMI aims at restoring motor or cognitive functions in patients with physical or cognitive disability, such as stroke survivors. In the near future, neuroenhancement could, instead, enhance performativity in healthy users. A debate on which types of enhancement should be allowed and under which circumstances shall be urgently placed on the agenda. Even nowadays, there are plenty of private companies that have already put on the market non-invasive BMIs designed for healthy users for such purposes as self-quantification, cognitive training, neurogaming (i.e., videogaming by means of brain control for recreational or competitive purposes) and polysomnography. Several companies, such as *Emotiv*, based in San Francisco (California), publicly claim (though without solid scientific evidence) that they are capable of enhancing "mental well-being" and "focus" of cognitively healthy users[17], i.e., applying forms of neuroenhancement. It is also worth saying that actual BMI designed for motor control already allows users not only to enhance pre-existing abilities, but also to acquire new ones: firs of all, telepathic control of robotic devices such as drones and other semi-autonomous vehicles – a very attractive ability in the transport and military industry[18]. In the near future, both the spread of similar (and new) technologies and the scientific corroboration of their operating mechanisms will make it impossible to avoid the ethical issue deriving from the application of neuroenhancement techniques.

III. Legal implications: from neurotechnology to neurorights?

8. Ethical challenges set by BMI and other neurotechnologies force us to face a fundamental issue of ethical, social and legal nature: to determine whether and under which circumstances it is legitimate to access or interfere with one's neural activity[19]. An answer to this question should be provided from different levels of jurisdiction, including research ethics, technology governance, civil and criminal law. Moreover, the problem at issue should be also discussed in terms of fundamental human rights[20]. The motivation is threefold: first, scientists explain neural activity as the critical substrate of personal identity, thus as the critical substrate of both moral and legal accountability too. It then follows logically that decoding and manipulating neural activity by means of neurotechnology may have unprecedented repercussions on users' personal identity and may provide them with a sort of "blurring effect", or even produce a real threat in terms of uncertainty when it comes to determine moral and legal accountabi-

[15] See F. Gilbert, M. Cook, T. O'Brien, J. Illes, "Embodiment and estrangement: results from a first-in-human 'intelligent BCI' trial", *Science and Engineering Ethics*, 2017, https://doi.org/10.1007/s11948-017-0001-5..

[16] See A. Ferretti, M. Ienca, "Enhanced cognition, enhanced self? On neuroenhancement and subjectivity", Journal of Cognitive Enhancement, 2018, 2, 4, pp. 348-355.

[17] See https://www.emotiv.com/.

[18] See M. Ienca, F. Jotterand, B.S. Elger, "From healthcare to warfare and reverse: How should we regulate dual-use neurotechnology?", *Neuron*, 2018, vol. 97, *n°* 2, pp. 269-274.

[19] See M. Ienca, "The right to cognitive liberty", *Scientific American*, 2017, vol. 317, *n°* 2, p. 10.

[20] See M. Ienca, R. Andorno, cit.

lity. Secondly, brain activity can be ascertained by every human being irrespective of gender, country, ethnicity and religious or political beliefs. Lastly, neural data not only codify electrophysiological information, but also provide, as already highlighted, evidence of mental activity. Mental domain, according to a well-established tradition that goes from Homer, via John Milton, to George Orwell, is considered the private domain par excellence, a sort of unattainable territory of private information, and, as such, it should be protected from "erosion", i.e., from the widespread intrusion of data society.

9. Nowadays, we are in the middle of an extraordinary historical transition. Data society and data economy are rapidly absorbing information domains that had always been private. These days, private houses equipped with microphones and television cameras recording our movements and conversations are nothing out of the ordinary. Public areas are almost entirely under video surveillance. Every website that we visit keeps track of our personal information on the client side and stores it in the long term by means of cookies HTTP. Every single online behaviour, every single entry on any online search engine, every online transaction by means of credit card - they are all processable information about us. The films we watch, the music we listen to, the things we purchase, the news we read - none of that belongs anymore to the private domain. The next decade will be essential for this unprecedented transition we are currently experiencing. Our generation will be remembered either as the one that has completed the process of private information's "erosion", by allowing data economy to have free access to the mental domain or, contrarily, as that one generation that fought on the barricades of human mind, preserving mental domain as the ultimate refuge of private information.

10. Facing the challenge of human rights in relation to neurotechnology seems to be more important than ever. A recent comparative study has suggested that actual protection and safeguarding measures may be inadequate – or at least not agile enough – to face properly the specific set of challenges raised by recent advances in BMI and neurotechnology in general[21]. As an example of regulatory uncertainty in this respect, it could be mentioned the so-called right to mental integrity, protected by the Charter of Fundamental Rights of the European Union (Art. 3), stating that "everyone has the right to respect for his or her physical and mental integrity". The right to mental integrity, mentioned together with the right to physical integrity, bases on three requisites: free and informed consent, non-commercialisation of human materials (e.g., human organs) and prohibition of eugenic and human reproductive cloning practices. Nevertheless, there is no explicit mention of practices related to the improper use of neurotechnology. For example, no mention is made of potential infringements to the right to mental integrity deriving from the hacking of BMI and/or neurostimulation devices such as deep brain stimulation (DBS). In this regard, it has been experimentally proved that such neurotechnologies could be hacked by malicious actors in order to hijack data and take control of the neurodevices. This attack mode could produce negative consequences for targeted victims, such as: unauthorised extraction of mental information, taking away from the victims conscious control of their robotic limbs, and even serious physical and psychological damages deriving from the intentional intensity increase of the neurostimulation.

11. This lack of mention can be explained considering that the European Charter was adopted in 2000; at that time, the debate on ethical and legal implications of neuroscience was still in the early stage. Though, potential applications of nowadays' neurotechnology open up to a set of intrusive practices that work in a comparable way to how genetics and other biomedical practices may influence personal integrity. For this reason, the legal framework should keep pace with neurotechnological advances, by extending protection of personal integrity also to people directly affected by new technologies.

12. On the basis of these comparative reflections, it comes naturally to wonder whether there is a real regulatory need in terms of creating an interpretative apparatus of human rights that would take into account new possibilities and threats generated by neurotechnologies. Another question might be whether it is rather necessary to create a new specific category of human rights for the neural domain,

[21] *Ib.*

called "neurorights". In this respect, a fair proposal was put forward by Ienca & Andorno by outlining four main neurorights[22].

13. The first neuroright is the right to "mental privacy", which is supposed to protect BMI users (and, potentially, also participants in neuroimaging procedures carried out in extra-clinical contexts, such as neuromarketing operations) from those three threats to personal privacy mentioned above. According to its positive connotation, the right to mental privacy should safeguard the distinction between neural information and unconscious access to it, especially in the case of information acquired from below the threshold of conscious perception. It has been already argued that some people may be more exposed to infringements of mental privacy, compared to other information privacy domains, due to their limited degree of control over brain inputs[23]. Indeed, it is well known that several recording technologies of brain activity, such as EEG and fMRI, take place below the threshold of brain conscious control. Therefore, patients do not have power of choice as regards letting access to given brain inputs, keeping whereas privacy over other inputs that should remain private.

14. The second neuroright is the right to psychological continuity, which could help in the integration process of AI and BMI, preserving personal identity – here understood as continuity of one's mental life – from unconscious manipulation. BMI users should preserve the right to have control over their own behaviour, without feelings of "loss of control" or even "personal identity damage"[24]. At the same time, the right to psychological continuity should also protect from unauthorised interference from third parties in BMI users' neural activity. For instance, users (already protected by the right to mental integrity) could be shield from unauthorised neuromodulation, even if it would not produce injuries nor traumas. The risk here would be to affect significantly users' psychological realm (for example, influencing their political and/or religious beliefs, emotional states and memories) without explicit consent. The neuroright at issue could then play a key role in national security and military research, being both fields in which neuroprocedures (such as neurostimulation techniques) are currently being tested for the modulation of given personality traits and other strategic purposes, like increasing soldiers' and other military personnel's work motivation and determination even under stress or in the absence of sufficient amount of sleep[25]. Such neuromodulation techniques are often applied by means of hybrid devices that can first detect signs of decrease of attention thanks to an EEG, then adjust it by stimulation.

15. The third neuroright is the right to mental integrity, as defined by Ienca & Andorno[26], which, instead, might help in cases of unconscious manipulation of neural activity and physical or psychological damages derived from it. As previously pointed out, this right is already recognized by international law (Art. 3, Charter of Fundamental Rights of the European Union), yet it is described as a merely general right, ensuring access to mental health services and prevention programs from eugenic practices. No mention is made of proper or improper use of neurotechnologies. Therefore, such right should be re-conceptualized in order not only to protect from mental disease, but also to circumscribe the domain of legitimate manipulation of neural processing.

16. The fourth and last neuroright is the right to cognitive liberty. This right was theorised in order to protect the fundamental freedom of human beings to take free and informed decisions concerning the use of BMI and other neurotechnologies, including neuromodulation techniques[27]. On the basis of this right, competent adults should be free to use BMI or neuroenhancement techniques for clinical purposes as long as they do not infringe on the rights of others. In parallel, users should also have the right

[22] *Ib.*

[23] *Ib.*

[24] See F. Gilbert, M. Cook, T. O'Brien, J. Illes, cit.

[25] See M.N. Tennison, J.D. Moreno, "Neuroscience, ethics, and national security: The state of the art", *PLoS Biol.*, 2012, vol. 10, n° 3, e1001289.

[26] See M. Ienca, R. Andorno, cit.

[27] *Ib.*

to refuse coercive requests for neural procedures, including implicitly coercive ones[28]. Additionally, the right to cognitive liberty could also facilitate, from a regulatory point of view, the introduction and the use of neurotechnology procedures on healthy individuals in extra-clinical contexts. By doing so, access to BMI would be allowed by default to adult individuals in full possession of their faculties, yet prohibiting coercive use by third parties (such as employers that would like to boost the work performance of their employees or insurance companies that would likely acquire neural information on their clients). That being said, it should be also necessary to keep in mind that there are some grey zones in between, such as in the case of people with neurocognitive disorders and adolescents, that should remain open to discussion. For the above-mentioned categories of users, the exercise of cognitive liberty should be determined case-by-case, evaluating the mental abilities of each individual.

IV. Regulatory uncertainty

17. The proposal to set up specific neurorights has been recently approved by experts of risk analysis[29] as well as by neuroscientists and neurotechnology researchers[30]. This proposal was also included in «A Proposal for a "Universal Declaration on Neuroscience and Human Rights"»[31], brought to the attention of the UNESCO Chair in Bioethics.

18. Nevertheless, a lot of issues still need to be tackled. First of all, there is the open question whether neurorights should be considered as new legal regulations or rather as evolutive interpretations of pre-existing human rights. Similarly, it is not entirely clear which entity should be the beneficiary of the rights under discussion: the brain itself, as recently put forward[32], or the individual as a whole? A final issue concerns grey zones within current legal and ethical dispositions, which should be investigated more carefully. For example, while it is well established that the right to cognitive liberty should protect freedom of choice of aware adults, it is questionable whether parents should have the right to give permission for the implementation of neuroenhancement practices on their children or whether family representatives should have the right to refuse neurotreatments with clinical benefits on behalf of a patient with cognitive impairment. Thus, it is required to face all these moral dilemmas in an open, public debate, involving not only scientists and ethicists, but also common citizens.

19. Besides, legal and ethical considerations should base on proven scientific evidence and realistic predictions, avoiding anti-technology narrative strategies driven by the fear that a transparent discussion on the issue might delay scientific innovation and cancel BMI-associated benefits for people who really need them.

20. It should be noted that the expansion of the present legal framework concerning human rights, aimed at responding adaptively to challenges set by neurotechnology and AI, is no *unicum* nor *primum* in the history of law. Experts in this field have been already called, and not just once, to undertake similar challenges in response to biomedical and biotechnological advances. An example of this comes from genetic technology. Since the late 1990s, the international community has made significant efforts in order to face a large variety of issues deriving from the increasing access to human genetic data. In 1997, the Universal Declaration on the Human Genome and Human Rights (UDHGHR) was adopted in order to prevent from gathering and improper use of genetic data in a manner which is incompatible with the respect of human rights as well as in order to protect human genome from improper

[28] See S.E. Hyman (2011), "Cognitive enhancement: promises and perils", *Neuron*, 2011, vol. 69, n° 4, pp. 595-598.

[29] See J. Cascio, "Do brains need rights?", *New Scientist*, 2017, 234, 3130, 24-25.

[30] See R. Yuste, S. Goering, G. Bi, J.M. Carmena, A. Carter, J.J. Fins, P. Friesen, J. Gallant, J.E. Huggins, J. Illes, "Four ethical priorities for neurotechnologies and AI", *Nature News*, 2017, vol. 551, n° 7679, p. 159.

[31] See F. Pizzetti, "A proposal for a 'Universal Declaration on Neuroscience and Human Rights", *Bioethical Voices (Newsletter of the UNESCO Chair of Bioethics)*, 2017, vol. 6, n° 10, pp. 3-6.

[32] See J. Cascio, cit.

manipulations that could damage future generations. In 2003, the main principles outlined in the Declaration were further developed in the International Declaration on Human Genetic Data (IDHGD). The latter contains more specific rules concerning the collection of biological samples and genetic data. It is interesting to note that brand new rights arose from the interaction between genetics and human rights, such as the "right not to know about one's genetic information", formally recognized by the UDHGHR (Art. 5 (c)) and by the IDHGD (Art. 10) as well as by other national and international regulations. In parallel with the recognition of new rights, the "old" ones – such as the right to privacy and the right to discrimination – were specifically adjusted to new challenges set by human genetics advances. The close connection between life sciences and human rights was further enhanced in 2005 with the publication of the Universal Declaration on Bioethics and Human Rights, in which both disciplines are tackled comprehensively, including also biomedical guidelines.

V. A roadmap for responsible neuroengineering

21. When discussing sensitive issues related to neurotechnology, it is fundamental to come up with both reactive and proactive considerations. Indeed, ethicists are called not only to merely react to ethical conflicts raised by new neurotechnological devices, but also to cooperate with neuroscientists, neuroengineers, computer scientists and medicine experts in order to anticipate future challenges and to promptly develop proactive solutions. Recently, it has been offered a new ethical approach in the neuroengineering field[33] that could be applied also to neurotechnology and biorobotics.

22. Furthermore, measured political responses should be discussed in order to guarantee the respect of the principles of equity and equality. BMI and other neurotechnologies should be, indeed, equally distributed without exacerbating social-economic disparities. To this end, a double-faced regulatory approach could be applied in a balanced way. On the one hand, access to BMI's healthcare services should be made available as widely as possible. Similarly, open development initiatives such as hackathon, open-source platforms (e.g., Open BCI) and data sharing initiatives led by the citizens should be encouraged. On the other hand, the increasing involvement of private companies in the development of BMI for profit purposes should foster debate on democratic responsibility related to technological advance in the private sector. In a not-too-distant future in which BMI would probably be extensively widespread, an increased need for trust will be surely reported – trust related to both acquisition and exchange of individual neural data. It is essential to maintain a high degree of trust in this respect not only for the technological advance in the neurotechnological field, but also for the development of new devices, capable of improving people's life. Failing in this attempt (for example, with a flawed data management affair similar to the one that involved Facebook and Cambridge Analytica), could produce deleterious consequences in the whole field of neurotechnological research. Hence the necessity of clear guidelines for collecting and using neural data, better infrastructures for the protection of neural data, greater public awareness and, as already discussed, greater development and implementation of neurorights. As recently stated[34], the development of technologies that could decipher the functioning of the human brain and, consequently, mitigate the negative impact of neurological disorders on affected patients, is one of the biggest challenges of our times in the scientific community. Similarly, the challenge that bioethics and law are currently facing in this regard consists in ensuring that technological advance takes place in an ethically responsible and socially friendly way.

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[33] See M. Ienca, R. Andorno, cit.

[34] See M. Ienca, P. Haselager, E.J. Emanuel, "Brain leaks and consumer neurotechnology", *Nature Biotechnology*, 2018, n° 36, pp. 805-810.