RAPPORTEUR REPORT

NEUROTECHNOLOGIES AND HUMAN RIGHTS FRAMEWORK

DO WE NEED NEW RIGHTS?

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INTRODUCTION

Recent advances in the field of neurotechnology such as brain computer interfaces (BCI) including deep brain stimulation (DBS) hold the potential to improve the diagnosis and treatment of mental and neurological conditions. According to the World Health Organisation (WHO), neurological conditions are the leading cause of disability adjusted life years (DALYs) and the second leading cause of death globally, accounting for 9 million deaths per year. Neurotechnologies[1] can record data about human brain structure, activity and function which can reveal information about a person's health status and can provided insights into brain processes as well as their link to mental states and observable human behaviours. Applications of the technology are not limited to the healthcare arena but are also finding expression in the domains of education, entertainment and marketing. As our understanding of the human brain increases, it becomes more likely that thoughts can be construed, shared and even modified. The ability to share data inferring someone's mental activity or to affect the way the brain functions by encoding brain activity rather than decoding it, poses a threat to privacy and personal freedom and identity. Thus, while recognising that developments in the field of neuroscience and neurotechnologies have offered and will continue to offer significant potential benefit for human health and welfare, a balance needs to be struck between technological development and respect for human rights, and consideration given to whether we have the legal and governance infrastructure and tools in place to deal with the ethical and social issues raised by current and future neurotechnologies.

Human rights principles such as human dignity, equality and non-discrimination provide a set of values to guide the innovation process continuum, from design to implementation. Attention to these principles should allow us to steer the innovation process in a way which connects innovation and technologies with social goals and values, thereby optimising the chances of stimulating innovation that contributes to human flourishing, whilst minimising applications that have negative consequences for individuals and society.

[1] Neurotechnologies have been defined as "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).

There has been significant scholarly and policy attention given to the legal and ethical challenges posed by neuroscience and neurotechnologies in recent years, with a number of proposals being made in respect of how best to govern neurotechnologies and their application both within and beyond the field of biomedicine. Such proposals have ranged from soft law instruments to the introduction of new "neurorights" including cognitive liberty, mental privacy, and mental integrity and psychological continuity. In 2019, the Organisation for Economic Cooperation and Development (OECD) adopted the OECD Recommendation on Responsible Innovation in Neurotechnology, the first international standard in the field of neuroscience to address ethical, legal and social challenges of these technologies. The Recommendation sets out nine principles to guide and support responsible innovation in neurotechnology at each step of the innovation process. Particular attention is paid to the importance of values such as stewardship, trust, safety, and privacy, enabling capacity of oversight and advisory as well as societal deliberation.

In 2021, the International Bioethics Committee (IBC) of UNESCO published a report on the ethical issues of neurotechnology which made a series of recommendations, including advocating for the adaptation of existing human rights and "to provide insights into the interpretation and application of existing human rights instruments…" [pg. 38, 2021] . The report calls on countries to guarantee the rights of its citizens by adopting laws that protect their right to mental privacy and freedom of thought, with a specific emphasis being placed on the rights of children and adolescents, given the potential impact of neurotechnologies on their developing brains and potential for an open future.

One of the core objectives of the Council of Europe Strategic Action Plan (SAP) on Human Rights and Technologies in Biomedicine (2020-2025) is to embed human rights in the development of technologies which have an application in the field of biomedicine. There is an explicit recognition that governance models are required which guarantee the protection of human rights throughout the entire process of research, development, and application. Moreover, ongoing dialogue between the public, scientists, and policy makers is required in order technological developments are robustly deliberated, democratic, and legitimate. Applications in the field of neurotechnology raise issues of privacy, freedom, autonomy, integrity, and discrimination. Whether these issues can be sufficiently addressed by the existing human rights framework or whether new neurorights are required to appropriately govern this fast-developing field remains an open question. International Human rights law makes no specific mention of neuroscience, although rights enshrined in the European Convention on Human Rights and the Convention on Human Rights and Biomedicine, such as the right to liberty, the right to respect for private life and freedom of thought, are clearly relevant in this context.

A specific action in the SAP is to assess the relevance and sufficiency of the existing human rights framework, to address the issues raised by the applications of neuroscience and neurotechnologies and to explore the most appropriate governance mechanisms for this field. As a first step in this process the Committee on Bioethics (DH-BIO) [2]commissioned Dr. Marcello Ienca, Principal Investigator at the College of Humanities at EPFL (Ecole Polytechnique de Lausanne), to produce a report providing a comprehensive normative-ethical, historical and conceptual analysis of neurorights. The report identifies priority areas for further academic reflection and policy work and concluded that reform was needed to adequately protect the freedom of a person's mind and brain in the neurotechnological era. It was suggested this could be achieved through adaptive interpretation of existing rights and/or through addition of new rights. To further explore this theme the DH-BIO at the Council of Europe and the OECD jointly organised a roundtable hybrid event entitled neurotechnologies and Human Rights Framework: Do We Need New Rights? on the 9th November 2021.

[2] As of January 2022, the DH-BIO has been replaced by the Steering Committee for Human Rights in the Fields of Biomedicine and Health (CDBIO)

OBJECTIVE OF THE ROUNDTABLE

The Round Table was jointly organised by the Council of Europe and the OECD in the light of the Memorandum of Understanding for Co-operative Activities between the CoE and the OECD adopted on 14 December 2020 by the two parties.
A preparatory group was established to plan and organise the Round Table, consisting of Mark Bale, DH-BIO Bureau member and UK delegate to the OECD Working Party on Bio-, Nano- and Converging Technologies, David Winickoff and Laura Kreiling, Secretariat of the OECD Working Party on Bio-, Nano- and Converging Technologies, Marcello Ienca, Consultant, and the DH-BIO Secretariat.

A group of Rapporteurs including Hervé Chneiweiss, Siobhán O'Sullivan (General Rapporteur), Alessandra Pierucci and Karen S. Rommelfanger were appointed to capture and report on the main findings and positions, conclusions, and recommendations emanating from the Round Table.

The Objectives of the Round Table were Threefold:

- Increase attention to the human rights issues raised by the applications of neurotechnologies in the biomedical field.
- Assess existing human rights frameworks to address them with a view to prevent abuses and misuses while promoting thereby innovations and applications that are beneficial namely for human health.
- Identify possible avenue for actions to contribute to responsible innovation in neurotechnology.

OPENING SESSION-OPENING REMARKS

► **Nicola Daniele Cangemi**, Head of Department for Human Rights, Justice and Legal Cooperation Standard Setting Activities, DGI, Council of Europe.

The evolution of technologies combined with the acquisition of knowledge on the functioning of the brain, open up the possibility of modifying and controlling the functioning of the human brain - to enter into the "cognitive intimacy" of individuals. Such intrusiveness makes it essential to reflect on the relevance of the existing human rights framework to ensure appropriate protection of our fundamental values related to *inter alia*, identity, autonomy, privacy, non-discrimination, and dignity. Mr. Cangemi noted that 70 years ago, the drafters of the European Convention on human rights could not have imagined the developments in medicine and science which have been realised in the second half of the 20th century and the issues such developments would raise in legal and ethical terms. It is no surprise, therefore, that in recent years the European Court of Human Rights has found itself grappling with human rights questions flowing from developments in biomedicine, albeit there have not been any cases to date dealing specifically with the question of neurotechnologies. Other bodies of the Council of Europe are however specifically addressing the human rights challenges raised by developments in neurotechnology. Mr. Cangemi reminded us that The Parliamentary Assembly adopted a Resolution in September 2020 entitled "The brain-computer interface: new rights or new threats to fundamental freedoms?", as well as a Recommendation calling for "support of the work within the DH-BIO on human rights and neurotechnology" and for consideration to be given to the "possibility of protecting 'neurorights' through an additional protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms". He welcomed the work being undertaken by the Committee on Bioethics, the OECD and UNESCO to promote innovations and applications in this field while ensuring they were responsible, in the service of human health and upheld fundamental human rights and freedoms.

► **Dirk Pilat**, Deputy Director of the OECD Directorate for Science, Technology and Innovation

Mr. Pilat pointed out that Neurotechnology offers opportunities to better understand the brain and treat illnesses that impact on human flourishing. However, neurotechnology also raises unique ethical, legal and social questions (e.g. privacy, autonomy, human enhancement, the regulation and marketing of direct-to-consumer devices, amongst others.) Mr. Pilat made reference to the ongoing work within the OECD to explore values, design principles, and a practical agenda for leveraging good governance for critical sociotechnical transformations. Both the 2019 OECD Recommendation on Responsible Innovation in Neurotechnology and the 2019 OECD Recommendation on Artificial Intelligence advance the view that we must innovate in a socially responsible and human-centric manner, embedding key values of social responsibility and human rights early on in the process of technology development. The fact that the Preamble of the OECD Recommendation on Neurotechnology cites the Universal Declaration of Human Rights underscores the value placed by OECD on a human rights approach to innovation. Further, he pointed out the need to anticipate developments in the field of new technologies and the requirement for inclusivity both in the development of new technologies, and in the dissemination and accessibility of such technologies. This can in part be achieved through multi-stakeholder dialogue.

► **Gabriela Ramos** (pre-recorded video), Assistant Director-General for the Social and Human Science of UNESCO

Ms. Ramos opined that neurotechnologies offer a glimpse of a new frontier and prospects which are both stimulating and concerning and raise unprecedented ethical risks and unique threatens to human rights. She made a distinction between neurotechnologies and other emerging technologies as they impact the brain which is central to human identity, autonomy, freedom of thought and human flourishing. Neurotechnologies store brain data, including emotional states, which renders mental privacy dangerously accessible. This is particularly problematic in the context of children and adolescents whose brains are still in a developmental stage and yet inferences could be drawn from their brain data. She pointed to the recently published report of the UNESCO International Bioethics Committee on the ethical implications of neurotechnologies which recommends that the existing set of fundamental rights at the international level be elaborated to address neurotechnologies. These rights should be aimed at ensuring the principle of informed consent as well as ownership of body and mind. She made reference to the future work of UNESCO in this area which will involve, amongst other things, work on developing universal ethical standards setting instruments to complement existing core human rights treaties and working with Member States to ensure that neurotechnoogies

are developed and applied in a way to benefit humanity. She also informed the participants that UNESCO would soon be adopting a recommendation on the ethics of artificial intelligence which recommends States develop guidelines for human-robot interactions.

While recognising the promise of neurotechnology in the biomedical field and beyond, the complexity of the issues raised by developments and application of these technologies needs to be acknowledged. There is a need to keep human rights and values to the fore from design to development to implementation stage to ensure innovations in neurotechnology can flourish in a socially responsible, inclusive manner which respects and upholds human rights.

SESSION I - SETTING THE CONTEXT

INTRODUCTION TO THE HUMAN RIGHTS ISSUES RAISED BY THE APPLICATIONS OF NEUROTECHNOLOGIES IN THE BIOMEDICAL FIELD

Chair: **David Winickoff**, Secretary of the Working Party on Bio-, Nano-, AND Converging Technology (BNCT) at the Organisation for Economic Cooperation and Development (OECD)

TECHNOLOGY AND THE HUMAN BRAIN

► **Rafael Yuste** (video recording), Professor of Biological Sciences and Director of the Neurotechnology Center, Columbia University, USA

Mr. Yuste began his presentation by defining neurotechnology as methods that could be optical, electrical, nano, chemical, magnetic and computational which seek to either (i) record the activity of neurons in the brain or (ii) to change the activity of neurons in the brain[3]. He pointed to the significant investment being made internationally in the last decade in neurotechnologies, including, the US Brain Initiative which has attracted funding of US$7 billion, as well as initiatives in China, in Korea, South Korea, Japan, Australia, Canada, Israel, and the European Union. In addition to these Government

[3] Neurotechnologies also have the potential to influence brain activity by impacting on astroglia activity.

initiatives, private industry has been investing heavily in neurotechnologies and last year outspent the US government by a factor of six. The principle focus of these efforts has been to develop a general theory of how the brain works, something we still lack, and is necessary to enable us to understand how the brain generates mental and cognitive abilities which define our humanity. Moreover, neurotechnology is urgently required to be able to diagnose, understand, and cure brain diseases. Mr. Yuste went on to give a number of examples of ongoing working in his and others' laboratories in both mice and humans to illustrate the progress currently being made in the field of neurotechnology. Images of objects can be implanted into the visual cortex of mice using neurotechnology, while mathematical models have been used to scan the brain activity of human volunteers and thereby determine what image the volunteer has in their mind. While brain decoding such as this in humans is at present rather primitive, with the application of AI it will be possible in the future to decode large scale brain activity of citizens. He also outlined invasive neurotechnologies including brain-computer interfaces which are allowing for patients with tetraplegia to operate robotics arms and providing prosthesis for those with peripheral blindness.

According to Mr. Yuste technological developments in the field of neurotechnology mean that we are on a path to a world where it will be possible to decode people's mental processes and directly manipulate the brain mechanisms underlying their intentions, emotions and decisions. Such advances could revolutionise the treatment of many conditions, from brain injury and paralysis to epilepsy and schizophrenia, and transform human experience for the better. However, the technology could also exacerbate social inequalities and offer corporations, hackers, governments new ways to exploit and manipulate people. Arising out of these concerns, the Morningside Group, comprising of neuroscientists, neurotechnologists, clinicians, ethicists and machine-intelligence engineers, have recommended the elaboration of new neural rights to protect citizens from unintended use of Neurotechnology. These rights include the (i) right to mental privacy, so that the content of our brain activity cannot be decoded without our consent (ii) the right to our own identity to our own self (iii) the right to our own agency so that our decision making remains under our control free from external influences (iv) the right to fair access to cognitive augmentation technology (v) protection from biases associated with the use of artificial intelligence algorithm in this new technology. These proposed rights recognise that the brain is not simply another organ and that our humanity is defined by our mental and cognitive abilities.

NEURORIGHTS AND EXISTING FRAMEWORKS

► **Marcello Ienca**, Principal Investigator and Head of the Intelligent Systems Ethics unit, Federal Institute of Technology in Lausanne (EPFL), Switzerland

Mr. Ienca acknowledged that neurotechnologies hold significant promise for promoting wellbeing and alleviating human suffering for those with brain and mental disorders but also raise ethical and legal challenges. Mr. Ienca opined that the brain is not simply an organ like all others, as the brain is the seat of thought, memory, consciousness and emotions, and defines personhood and our very identity. On this basis, it has been proposed that the challenges raised by neurotechnologies must be addressed not only with technical and ethical guidelines but also in terms of fundamental rights. Mr. Ienca and colleagues have suggested a series of neurorights as fundamental normative rules for the protection and preservation of human brain. He described some thematic neurorights which have been suggested, namely derivatives of (i) freedom of thought, (including cognitive liberties such as the right to mental self-determination) which establishes a link between action and agency; (ii) right to privacy, specifically mental privacy or the right to exercise control over one's mental information against intrusions and unauthorised access; (iii) mental integrity which is the counterpart of physical integrity, and needs to be protected from intended or unintended abuses; (iv) and personal identity to preserve the person from undesired modification of their personality.

Mr. Ienca then raised a number of open questions in relation to these new neurorights and noted that most rights are construed as negative rights (freedom from) rather than positive rights (freedom to) which could pose a challenge. However, he pointed to disability rights as a possible exemplar for neurorights in this regard. He pointed to the fact that neurorights are complex and multifaceted rights which are typically interpreted as both moral rights (i.e., rights in the philosophical sense) and legal rights (i.e., rights which exist under the rules of legal systems or by virtue of decisions of suitably authoritative bodies within them). Any future international declaration or legislative reform related to neurotechnology and human rights could benefit from being based on neurorights as moral rights. The study of neurorights should reflect on whether neurotechnology-related issues can be sufficiently addressed by the existing human rights framework or whether new human rights pertaining to the neurocognitive domain need to be elaborated in order to govern neurotechnologies. Another pressing question posed by Mr. Ienca relates to whether neurorights are to be interpreted as novel human rights or as an evolutionary interpretation of existing rights. He pointed to the importance of avoiding ‘rights inflation’, i.e., the objectionable tendency to label everything that is morally desirable as a ‘human right’. The unwarranted proliferation of human rights is problematic because it generates scepticism about all human rights, as it dilutes them to

mere desiderata or purely rhetorical claims. Notwithstanding the risk of such rights inflation, he pointed out that new declarations, rather than new rights, have been drafted with the aim of protecting human rights in light of technological advances. For example, progress in genetics, particularly in genome sequencing and editing technologies, was addressed by UNESCO in the International Soft Law Declaration on Human Genetic Data (2003) and The Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) (1997). Further, he suggested that the Oviedo Convention is a suitable framework for an examination of the protection and promotion of neurorights, be that through the prism of existing provisions or the development of an additional protocol.

RECOMENDATION OF THE OECD COUNCIL ON RESPONSIBLE INNOVATION IN NEUROTECHNOLOGY

► **Myong Hwa Lee**, Chief Director, R&D Strategy Research Division, Science and Technology Policy Institute (STEPI), South Korea

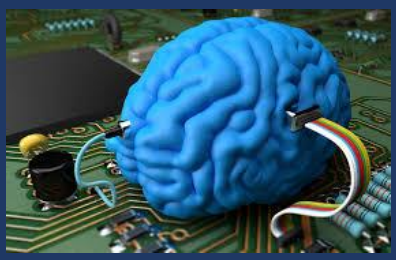
Ms. Lee provided an overview of the recent OECD Recommendation on Responsible Innovation in Neurotechnology which aims to guide governments and innovators to anticipate and address the ethical, legal and social challenges raised by novel neurotechnologies while promoting innovation in the field. A multi-disciplinary Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) was established in 2015 and developed the Recommendation in a step-wise process involving structured consultation and engagement with policymakers, key stakeholders and civil society. Ms. Lee outlined the significant potential novel neurotechnologies held for the promotion of health, well-being, and economic growth. Mental and neurological disorders are increasingly recognised as major causes of death and disability worldwide. Neurotechnology is redefining what is possible in terms of monitoring and intervention in clinical and non-clinical settings, with great promise for improving mental health, well-being and productivity. At the same time, neurotechnology raises a range of unique ethical, legal, and societal questions that potential business models will have to address.

It was noted by Ms. Lee that governance issues surrounding neurotechnology affect the entire innovation pipeline, from fundamental brain research, technology transfer, to questions of commercialisation and marketing. The OECD Recommendation seeks to support governments and innovators in addressing and anticipating the governance challenges raised by neurotechnologies. It sets out a number of principles for responsible innovation in neurotechnology including (i) Promote responsible innovation in neurotechnology to address health challenges; (ii) Prioritise assessing safety in the

development and use of neurotechnology; (iii) Promote the inclusivity of neurotechnology for health; (iv) Foster scientific collaboration in neurotechnology innovation across countries, sectors, and disciplines; (v) Enable societal deliberation on neurotechnology; (vi) Enable the capacity of oversight and advisory bodies to address novel issues in neurotechnology; (vii) Safeguard personal brain data and other information gained through neurotechnology; (viii) Promote cultures of stewardship and trust in neurotechnology across the public and private sector; (ix) and Anticipate and monitor the potential unintended use and/or misuse of neurotechnology. The implementation of the Recommendation is being supported by the development of practical tools and guidance. Including a collection of examples of best practices and lessons learned in the field of neurotechnology.

SESSION II- MAPPING THE LANDSCAPE

Chair: **Mark Bale**, Committee on Bioethics of the Council of Europe (DH-BIO)



MEDICAL FIELD

► **Carlo Caltagirone**, Neurologist and neuroscientist, Scientific Director at IRCCS Santa Lucia Foundation, Italy

Mr. Caltagirone gave an overview of the current state of play of neurotechnologies in the medical arena. He defined neurotechnology as the assembly of methods and instruments that enable a direct connection of technical components with the nervous system. These technical components are electrodes, optical fiber, computers, or intelligent prostheses. 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. In a broader sense can be included those technological tools used to diagnose and treat brain diseases. The aim is to develop (i) Experimental methods to study neuronal populations of the brain for diagnostic purposes (ii) New tools for neuro-pharmacology (iii) Assistive technologies for neuro-rehabilitation (iv) Artificial systems to mimic brain functions. Mr. Caltagirone suggested a classification of neurotechnologies as invasive/non-invasive, intrusive/non-intrusive, short/long-term effects, reversible/irreversible. He provided several examples of state-of-the-art research and applications of neurotechnologies for health purposes. These included *non-invasive brain stimulation* refers which modulate the excitability of the brain via transcranial stimulation.

Six TMS devices now have approved uses by the U.S. Food and Drug Administration and are used in clinical practice: five for treating medication refractory depression and the sixth for presurgical mapping of motor and speech areas. *Deep brain stimulation* (DBS) is a neurosurgical procedure involving the placement of a medical device called a neurostimulator (sometimes referred to as a "brain pacemaker"), which sends electrical impulses, through implanted electrodes, to specific targets in the brain for the treatment of neurological and mental disorders. DBS has been approved by the Food and Drug Administration as a treatment for essential tremor and Parkinson's disease, dystonia, obsessive–compulsive disorder, and epilepsy. Mr. Caltagirone also described *brain–computer interfaces* (BCIs) which can provide non-muscular communication and control for people with severe motor disabilities. This can be achieved by extracting information about user's intent to move directly from signals originating in the central nervous system. Technological advances in this domain are providing increasingly more powerful tools to study, restore, and augment neural functions. These technologies can be applied in different fields from rehabilitation after stroke to augmentative communication in people with severe disabilities.

Mr. Caltagirone noted that these developments in neurotechnology while offering potential treatments and therapies to patients also raised a number of ethical issues including *Data privacy* - how is neural data going to be used?; *Equality* - could the use of neurotechnology could increase inequality?; *Autonomy* – the use of neurotechnologies may cast doubt on the idea of the self as decision maker?; *Normality* - the potential to restore lost function raises the question of what is ‘normal functioning?

NON-MEDICAL FIELD

► **Peter Reiner**, Professor of Neuroethics, Department of Psychiatry, University of British Columbia, Canada

Mr. Reiner outlined that neurotechnologies are easily available direct to consumer and can do a variety of things in non-medical fields. They fall into essentially two different camps. The first is technologies which can sense, read, or record brain activity in some way, the second can intervene with or write brain activity in some way. The current state of the art of consumer level neurotechnologies that sense brain activity is actually relatively crude. The most popular device for the purpose of recording brain activity are EEG (electroencephalogram) headbands. Consumer-grade EEGs utilize electrodes that sit under that headband on the head of the consumer (on the contrary to clinical level EEG that have many electrodes). The placement of those electrodes by the consumer has a significant effect on the granularity of brain activity that it might record. Such headband tends to be used to get a coarse sense of general EEG pattern which are

reported to offer insights as to whether an individual is in a relaxed state or not. People use it to help them meditate or the help them to fall sleep. The number of applications for this brain sensing headband currently remain relatively limited. It's been on the market for half dozen or more years with limited success. An EEG headband is able to collect some neurospecific data and some EEG, with low information quality. Thus, currently keeping private the ideas is not at risk, whereas perhaps users may be at risk of having others know their arousal state such as awake, focused on a task, or relaxed. Mr. Reiner pointed out that future developments may allow a much more refined analysis and interpretation of a person's brain activity. For example, by utilising implanted electrodes, impressive progress has recently been made in the analysis of cortical activity allowing speech in patients who have lost the ability to do so, and it might be possible in the future to record non-spoken answers to questions just from an EEG recording. One can see the utility of such technology in the compensation of disability after a stroke but it also has applications in non-medical settings. Providing AI deep-learning programs with a great deal of information on how our brain cortical activity produces our speech could allow transmitting speech without the need to voice it. Mr. Reiner also gave the example of Transcranial Direct Current Stimulation (tDCS), which are also available as a direct-to-consumer devices which can affect neuronal activity. While the effects of tDCS for these purposes remain controversial, devices have been on the market for the last six years, with the promise of improving locomotor activity and learning.

In the view of Mr. Reiner, applications of neurotechnologies in the non-medical field raise a number of human rights concerns. He notes that all neurotechnologies described by him require active participation by the consumer. Questions of whether rights are violated or not depends on the kind of information provided to the end user, who has to give their consent/agreement to using such technology. He noted that most end users sign off agreements without any detailed examination of the terms and conditions attaching to use of the technology. He observed that currently, use of neurotechnologies in non-medical contexts attract minimal to no regulatory oversight which raises the possibility that neural data may well be used for purposes other than those the consumer would necessarily agree. He also notes that minimal risk for safety, inexpensive costs, application in the non-medical field, make them out of reach of regulators. While observing that neurotechnology devices currently available to the consumer are rather crude in nature, this is likely to change in the next decade.

SESSION III- RIGHTS AT STAKE

Chair: **Marcello Ienca**, Leader of the Intelligent Systems Ethics Group. College of Humanities, Swiss Federal Institute of Technology in Lausanne (EPFL), Switzerland

PRIVACY

- **Giancarlo Malgieri**, Associate Professor of Law at EDHEC Augmented Law Institute, France
- **Fruszina Molnár-Gábor**, Research group leader at the Heidelberg Academy of Sciences and Humanities, Germany
- **Olaf Blanke**, Bertarelli Foundation Chair in Cognitive Neuroprosthetics Center for Neuroprosthetics & Brain-Mind Institute Swiss Federal Institute of Technology (EPFL), Campus Biotech, Geneva, Switzerland

Giancarlo Malgieri highlighted that there is a new challenge for human right lawyers and others: the possibility to access and read, but also to control, influence and direct the human mind. There are two main areas worthy of exploration: the first one is intrusion as *observation* of human mind, and the second, which is the main concern for lawyers, is intrusion as *influence/manipulation* of the mind. There is already a mosaic of existing/traditional elements such as freedom of thought, privacy, personal identity, integrity which represent a specific and necessary, although possibly incomplete, perspective to react to the manifold implications of neurosciences on human beings. According to Mr. Malgieri, we should be aiming for a comprehensive approach capable of reacting to the threats raised by developments in neuroscience and better protecting human rights. This raises the question of whether we should introduce new rights (new protocols, new multilateral instruments, etc.) or rather use interpretative guidelines regarding the rights enshrined in existing legal instruments. The experience of the European Court of Human Rights (ECtHR) has shown that existing rights such as the right to private life (Article 8 ECHR) can be considerably expanded to allow a broad protection of the individual, including her integrity. For example, Article 8 started as a protection from intrusion by public authorities but, via its evolutive interpretation, was expanded to cover integrity, including mental integrity. As noted by Mr. Malgieri, although

within a sometimes “fragmented” picture conditioned by the different semantics used by judges, moral and mental integrity have been also emerging in the jurisprudence of the ECtHR in the last few decades.
Mental integrity, in the case-law of the Court, is connected to Article 3 ECHR, namely the prohibition of torture and some cases extended the torture and the right to family life to encompass mental integrity. The concept of home was also considered central to self-determination. He raised the interesting notion of whether the concept of home could be extended to the brain as the “home of our mind”, by reference to Article 8. Mr. Malgieri concluded by posing the question of whether we should continue to explore the evolutionary interpretation of existing rights rather than elaborate new rights in the field of neurotechnologies and suggested that secondary legislation, could be an alternative way forward.

Fruszina Molnar-Gabor noted that according to ECtHR case law, the right to privacy includes both internal and external content that protects the human personality in its identity, individuality, in its physical and mental integrity, in its sovereignty relating to the information about one’s private affairs and her personal interaction with other people. One of the dimensions of the right to privacy is the right to be forgotten, the purpose of which to prevent the preservation of information about a person which may stymie the free development of her personality. In the neurosciences the concept of forgetting gains internal and external importance due to the close relationship of data with the data subject and due to the often-unconscious generation of data which makes it more difficult to distinguish which data serve as a basis for decision-making by others, and which data will return to the data subject in some form including as part of a decision. Therefore, the connection between one’s own and other’s forgetting is intertwined with internal and external relational privacy and is also as a manifestation of negative and positive freedoms that should not be overlooked. Although human rights law and ethics have gained importance in the discourse around neurotechnologies, the relationship between human rights and ethics remains contested in particular by applied ethics. From the perspective of law, it could be said that ethical principles become legal only when they are framed in their concrete form in compliance with formal and material legal requirements. However, ethical principles can become binding in many ways, for example when codes of conduct integrating ethical principles become legally binding through their legal system. Recourse to ethics committees mandated by law or the establishment of data trustees are also example of integration of ethics in legal tools. Ms. Molnar-Gabor highlighted that in a fragmented landscape of different legal frameworks, specific attention should be given to the Council of Europe Convention 108, the only legally binding instrument at international level for data protection. This legal instrument ensures that personal data originally processed in a jurisdiction bound by the Convention are

appropriately protected once transferred to a country which is not party to the Convention, including in respect of the necessity and proportionality principles.

Olaf Blanke noted that neurotechnologies raise unprecedented ethical and legal challenges in respect of privacy. He highlighted that a new research field at the confluence of neuroscience, engineering, medicine and computer science is emerging aimed at understanding the brain, in particular in respect of some very serious diseases such as Parkinson's and Alzheimer's. Neurotechnologies offer the potential to 'read' and 'write into' the brain and it is the 'writing into' the brain which in particular raises fundamental issues. As 24-7 closed loop DBS demonstrates, scientists/clinicians can access to motor data and emotional states and cognitive activities including the patient's sense of agency (e.g., movement and intention); A neuroethics framework is needed to safeguard and/or give special consideration to these kinds of data. Access to such neural data poses clear and immediate risks in relation to personal privacy, raising crucial questions such as: who (company/organisation/government) has access to the data related to the patient which provides insights into the inner state of the person being monitored. There is also the question of how neurotechnology resources should be fairly allocated and how decisions regarding those who can access such novel technologies should be made. Mr. Blanke noted that neuroactivity is what/who we are; it is not only connected to memory but also to identity and selfhood. Reading and even writing into neural activity, could mean changing memory and identity, and as such raises profound ethical and legal concerns. Mr. Blanke concluded by observing that neurotechnologies, advanced neuro-ethics, law-making and international diplomacy have to align and move together from the earliest research phase to provide adequate protections for human rights. This could be facilitated by fostering interaction and collaboration at all levels of scholarship, from the youngest to the very advanced researchers.

MENTAL INTEGRITY

- **Emily Cross**, Professor of Social Robotics, University of Glasgow, and Professor of Human Neuroscience, Macquarie University), member of the UNESCO International Bioethics Committee (IBC), Australia
- **Jakob Elster**, Associate Professor Norwegian Centre for Human Rights, University of Oslo
- **Judy Illes**, UBC Distinguished University Scholar, Professor of Neurology, and Director, Neuroethics, Canada

Ms. Cross posed the question of how we define mental integrity? She pointed out that conceptually mental "integrity" has been complicated and evolving. Historically mental and psychological integrity are used as counterparts to physical and bodily integrity such

as with Article 3 of the EU Charter of Fundamental rights. That is, the inviolability of the human body and autonomous control of the body is protected by legislation. In a similar way, the inviolability and autonomous control of the mind would be considered a key feature in protecting mental integrity. While explicit physical integrity protections exist, explicit protections for mental integrity are rare. An example where mental integrity is mentioned can be found within the Oviedo Convention. She opined that the looming challenge and reality is that there is no bright line that can easily be drawn between physical and mental integrity. Evolving science has made clear that physical activity of the brain enables mental integrity and versa is possible as well.

Mr. Elster reiterated that conceptual clarity on 'mental integrity' is critical to avoid the challenge of simultaneously protecting too little and too much in formalisation and implementation of any calls for policies on mental integrity. For example, a call in some neurorights proclamations have proposed restrictions of harmful mental interference. He noted that Thomas Douglas and Lisa Forsberg, in their discussions of mental integrity, state that a medical ethics framing of 'bodily integrity' includes the right to not be touched unless consent is given. He observes that the equivalent for mental integrity might be the right not to have one's mental states altered without consent. This is a rather challenging proposition, as while it is possible to interact with other members of society without nonconsensual touching, it's quite impossible to live in a society without changing other people's mental states. Rather than mental integrity, Mr. Elster suggests another framing is a right to be free of harmful mental interference as suggested by Ienca and Adorno. But this approach is also unsatisfactory: In practice, one could argue that telling someone that "your wife is cheating on you" could be equated to harmful mental interference and we have no restrictions on this kind of activity. An unspecified constraint on "mental integrity" might also be too paternalistic, such as disallowing medical inventions that used to alleviate depression. An alternate approach could be to focus on the form the interference takes (rather than whether it is 'mental' or an 'interference with mental states' that is harmful). For example, looking to form could be illustrated by a salesperson attempted to sell a car. Seeking to influence mental states via the form of conversation would still allow for the potential buyer to autonomously decide on whether to purchase the car. However, a salesperson who attempted to hypnotize the individual, would take a form that potentially undermines the potential buyer's ability to decide on their own. If we focus on the form of interference, we can create a solution that protects against forced interference that bypasses reasoning and capacity for autonomous choice.

Judy Illes, grouped mental integrity with dignity and rights. She highlighted the need to acknowledge the culture, knowledge and meanings associated with 'right' and 'integrity' if we are to consider departing from existing ethics frameworks and generating new ones in the case of neuroethics, such an inclusive approach is essential to insuring dignity of

individuals. She also suggests that the case of neuroscience and neurotechnology are unequivocally an exceptional case that warrants deep and unique consideration. In the context of considering neurorights, she urged that priority should be given to promoting neuroscience and technology development that alleviates public health burdens such as disease and inequity in accessing basic resources e.g., water security. She also noted the importance of the dimension of responsible conduct of research in neurorights, such as ethically guided research and particularly with first-in-human trials. An inclusive approach would be borne out by harmonised principles across nations and assurance that neurotechnology innovation would not further marginalise already disenfranchised patients and people across the globe.

FREEDOM

- **Susie Alegre**, International Human Rights Barrister, Associate, Doughty Street Chambers, UK
- **Miguel Cabral**, Public Health Medical Doctor, Public Health Unit of Maia/Valongo, Portugal
- **Pieter Roelfsema**, Director of the Netherlands Institute for Neuroscience in Amsterdam

Ms. Alegre stated that the Universal Declaration of Human Rights has two significant articles related to freedom, Articles 18 and 19. In these articles related to freedom of thought, conscience, religion and freedom of opinion and expression, together we can see the roots of rights that are intended to aspects of the inner state of mind. Article 19 also emphasises the freedom to hold opinions without interference and impart information and ideas through any media. The human rights committee of the UN as stated in General Comment 22 was intended to be *"far-reaching and profound; it encompasses freedom of thought on all matters, personal conviction and the commitment to religion or belief, whether manifested individually or in community with others…"*
Ms. Alegre observes two critical features of these rights are absolute protection of the 'forum internum" and qualified protection of manifestation and expression of the forum internum. She notes that protection of the forum internum is one of the few absolute human rights (e.g., torture and slavery prohibition) which goes to the core of protecting what it means to be human. Therefore, the right to freedom of though is key to neuroscience and protection of human rights. Ms. Alegre argues that while we must investigate how to protect these rights, we already have the rights we need via existing international human rights law. She described three critical concepts currently covered by existing law and the protection afforded for the 'forum internum', (i) Mental Privacy: right to keep thoughts/opinions private and an absolute call of mental privacy in the UDHR (ii) Cognitive Liberty: right not to have thoughts and opinions manipulate. Noting that

manipulation is different from influence (iii) right to lack of mental interference: right not to be penalised for one's thoughts or discriminated against based on actual or assumed thoughts. She expressed caution regarding a combination of a political and scientific landscape that could inadvertently through rights inflation, result in "fewer rights than we started with…stripping us of fundament rights that we've worked so hard to create". She closed with a series of questions to be explored in further defining the Forum Internum

- Where is the boundary between thought and manifestation?
- Where is the line between legitimate influence and manipulation?
- Can risky thoughts ever be used to predict risky behaviour?
- What can be considered as consent for an interference with the forum internum in the context of neuroscience?

Mr. Cabral offered an alternate view, noting that we have an infrastructure to protect abstract concepts, but in practice are difficult to engage. For example, conceptual models of freedom are based on the intangible, but in practice model must be based and applied to behaviors. With neurotechnologies, societies may be able to address the intangible thoughts with tangible behaviors based on neuronal activities that become thoughts. In other words, a paradigm shift from a practical point of view because the tech may change our freedom of thought everywhere at any time without possible awareness from the individual. Mr. Cabral suggested that thoughts are already apprehended to a certain degree by current technologies such as via social media. Furthermore, thoughts could be considered even manipulated by social media giants. While these technologies might be interpreted as constraining freedom, some technologies can certainly be enablers and can empower agency such as with technologies that could prevent numerous mental conditions (e.g., depression, suicidality, epilepsy, and psychosis) as well as prosthetics that are able to restore senses (e.g., hearing, seeing, feeling). Neurotechnology in the future may pose an even greater threat because we may be less able to track and prevent threats to freedom and manipulation directly to the brain.

Mr. Roelfsema provided a deeper look into the state of the art of neurotechnology in creating visual prosthetics. He noted that the neurotechnology he and his colleagues were developing was meant to restore some level of freedom and independence such as with navigation, reading, and ability to read body language and facial expressions. Additional considerations may need to be considered as predictions of behavior are made based on neurotechnologies. Complications may arise with predicting risk for diseases that currently lack a viable treatment or cure or might further influence definitions of what we consider "normal" versus what we define as a disease or possibly lead to greater discrimination. Mr. Roelfsema noted that the process to develop a brain computer interface is lengthy and it will be some considerable time before it is available to larger

groups of individuals experiencing blindness. With neural prosthetics for vision, there is not currently the capability to influence higher thought processes other than helping to resolve visual streams, however Mr. Roelfsema urged that ethical priority should be toward restoring freedom via empowering independence with neurotechnology.

NON-DISCRIMINATION

- **Nita A. Farahany**, Robinson O. Everett Distinguished Professor of Law & Philosophy and Founding Director of the Duke Initiative for Science & Society, USA
- **Philipp Kellmeyer**, Neurologist, Head of the Neuroethics and AI Ethics Lab, University Medical Center Freiburg, Germany

Nita Farahany highlighted the similarities between genetic data and neuro data that make the reflection on genetic data a starting point for constructing the discourse on the risks raised by neurodata. However, she also highlighted the differences between the two which deserve consideration, e.g., contrary to genetic data, neuro data are not static and merely probabilistic. Neurological information is not only based on propensity but also includes information on current cognitive and affective states. Ms. Farahany noted that the use of AI in conjunction with neurotechnologies introduces additional risks for individuals, in particular risks of bias and lack of transparency. She also pointed out the need to be vigilant in respect of discriminatory risks posed by the increasing use of neurotechnologies in education, work, play. Evaluation of students as well as employees in terms of educational attainment, hiring/firing practices and promotional opportunities divorces actual and overall performance from propensity and determinism which can generate discrimination and exclusion. Neurotechnologies may allow employers to detect cognitive decline or early evidence of neurological diseases which could be used to preemptively fire an employee for reasons that would not be ordinarily permitted. There are risks also when we introduce neurotechnologies into play, in particular in respect of the way we judge art, beauty, music. According to Ms. Farahany, being aware that we constantly make choices on the basis of cognitive abilities (for example occupational choices), we should try to draw the line between ordinary and unacceptable use of neurotechnologies and define when such use produces unfair treatment of individuals or groups. She notes that drawing the line between what is a legitimate use of neurotechnologies is not an easy exercise. In determining legitimate uses we need to understand when inferences are used in a probabilistic or deterministic way.

Philipp Kellemeyer focused on the different strategies for bias mitigation. He underlined the strong relationship between neurotechnologies and A.I which are now giving birth to a "*technological superconvergence*" and described the different categories of bias in human decision making, namely cognitive (mental shortcuts that lead to distortions of our

decision making) and societal bias (cultural bias, discrimination, structural injustice). He then considered the technical notion of bias in statistics and machine learning (variance dilemma) and highlighted that bias is “everywhere” even in the simplest computer program (coming from the program itself, the data used and even from the users). In respect of the possible strategies for bias mitigation, he mentioned (i) fair machine learning e.g., using representative data samples for training (ii) developmental AI (iii) de-biasing of human decision-makers (iv) “nudging“ or structural bias control (v) limiting the use of AI in socially sensitive applications. Mr. Kellemeyer highlighted the process of “de-biasing” in human decision making, which in theory means training individuals (or algorithms) to recognise their own biases and actively avoid them, but which in practice can be difficult. He then moved to bias in neurotechnology and highlighted that technical and structural biases raise regional and global questions of comparability, fair access and structural injustices and investigated on the strategies for responsible and fair neurotechnology. He also highlighted the problem of bias in neuroscience research, in particular methodological bias and finally observed that in neurotechnology there can be a problem of societal bias, so called “*technosolutionism*”, namely the tendency to seek solutions to societal problems through the means of technology, rather than consider alternative strategies. He concluded that in order to build up efficient strategies for responsible and fair neurotechnology we need to consider new techniques for de-biasing, work on a representative and inclusive neuroscience and neurotechnology research and develop an opensource and participatory research and development approach to AI and neurotechnology.

SESSION IV- NEW RIGHTS OR STRENGTHENING EXISTING HUMAN RIGHTS?

Chair: **Siobhán O'Sullivan**, Vice-Chair Committee on Bioethics of the Council of Europe (DH-BIO)

- **Morten Ruud**, Chair of the Steering Committee for Human Rights (CDDH), Council of Europe
- **Paula Martinho** da Silva, Member of the UNESCO International Bioethics Committee (IBC)
- **Françoise Roure**, Chair, Working Party on Biotechnology, Nanotechnology and Converging Technologies, OECD Chair, Committee Security, Safety and Risks, Ministy of Economy and Finance, France
- **Abel Wajnerman Paz**, Professor and Director of the Neuroethics Group, Department of Philosophy, Alberto Hurtado University, Santiago, Chile
- **Henry T. Greely**, Professor by courtesy of Genetics, Stanford School of Medicine; Director, Center for Law and the Biosciences; Director, Stanford Program in Neuroscience and Society; and Chair, Steering Committee of the Center for Biomedical Ethics, USA

Mr. Ruud advanced the view that rather than speaking about new human rights it might be more helpful to consider the adaptation of existing rights which could be applied to the

field of neurotechnology. He pointed to the fact that the European Convention on Human Rights already contains a number of articles, namely 8, 9 and 10 which are relevant in the context of the challenges posed by novel neurotechnologies. This would require a broader interpretation of these rights and in this regard, he gave the example of the need to conceive of consent in its widest form i.e., not just consent to treatment but also to having our brains monitored even if non-invasively. Mr. Ruud opined that depending upon existing legal rights instruments however may not be sufficient to govern novel neurotechnologies, and that they will need to be supplemented by global standard setting in this area. In this regard he pointed to the development of Council of Europe tools such as the Convention on Human Rights and Biomedicine. He suggested that rather than elaborating new international rights instruments, which brings its own challenges, not least of which is reaching international consensus on what should be protected, legal binding regulation e.g., through national legislation, either primary or secondary, might be a more efficient option and would allow for sanctions for those who violate protected rights.

Ms Martinho da Silva continued with this theme and acknowledged that there was a need to recognise and protect neuro-rights. She however pointed out that human rights are constantly under threat from developments in emerging and converging technologies and as such, rather than speaking about new neuro-rights, from a legal perspective it might be more useful to speak about protection against new threats to existing human rights. She noted that "*we live in law saturated society*" and we must be cautious about which new rights (if any) to introduce. Further, any new neuro-rights introduced would have to be applicable, effective and implemented in a way in which citizens could comply with them. She observed that rights already enshrined in national, international laws and international human rights instruments: human dignity, integrity (either physical and mental), privacy (here mental privacy), freedom of thought, free will, equality, non-discrimination (in the access to new technologies) could all be applicable in the context of neurotechnologies. By way of illustration, she gave the example of advances in recent years in genetic technologies. The right to privacy and the right to non-discrimination were both successfully adapted to address the novel challenges posed by genetics. This may provide a template for how neurotechnologies can be regulated. For example, neural data could be encompassed within a broad/flexible definition of personal data and the scope of Article 9 of the EU general data protection regulation 2016/679 could be extended to include non-authorised reading and modification of neural data. She cautioned that prior to the introduction of new neuro-rights it would be important to clarify the concept of normal brain functioning which is challenging given current knowledge deficits in this regard, as this would be necessary to distinguish between use of neurotechnologies for treatment and neuro-enhancement. Finally, she pointed out the need to review regulatory

protections for the application of neurotechnologies outside the field of medicine e.g., commercial uses and to ensure robust protection for vulnerable users.

Ms. Roure advanced the view that in determining how to regulate neurotechnologies there was a need for societal deliberation and collaborative work between international bodies such as OECD, Council of Europe and UNESCO. She argued that converging on a common binding legal instrument may not be either necessary or desirable and we need to facilitate the responsible innovation in the field of neurotechnology as it holds great promise within and beyond the field of biomedicine. She particularly emphasised Principle nine of the OECD Recommendation on Responsible Innovation for Neurotechnologies, namely to anticipate and prevent misuse of these technologies, including short and long-term negative impacts. This should include an ethics-by-design approach to the development and dissemination of neurotechnologies to ensure that the technology remains under societal control. She favoured the establishment of mechanisms to preserve integrity, dignity, autonomy of individuals, as well as protection of private life, and non-discrimination. Activities aimed at influencing the decision-making processes of individuals or groups by limiting liberty and self-determination e.g., by intrusive surveillance, should be anticipated and protected against, and to the greatest extent possible there should be concrete actions taken to safeguard against potential abusive uses of neurotechnologies. In Ms. Roure's view this could be achieved through governance mechanisms including "soft law". She pointed to further actions by the OECD in this field including mapping good practices of members states in adhering to the OECD recommendation. She also mentioned the establishment of a French taskforce including private sector participants, to elaborate a charter to ensure the main principles of the OECD Recommendation are upheld and respected.

In 2021, Chile became the first country in the world to protect neuro-rights with the introduction of a Bill amending the Chilean Constitution. **Mr. Wajnerman Paz** gave an overview of the development of the Bill which sets out to protect the right to mental privacy, personal identity, the free will of thought, equitable access to technologies that increase human capacities, and protection against discrimination. Mr. Wajnerman Paz pointed out that there were at least four kinds of questions regarding neurotechnologies that are being addressed within the Latin-American context: issues related to neural data privacy, issues related to direct-to-consumer neurotechnology, the kind of legal liability of neurotechnology companies and "neurocrime "or criminal acts related to neurotechnology. Regarding neural data privacy, part of the discussion on the protection of neural data suggested that it may require a stronger protection than other kinds of sensitive data, being ontologically closer to an organ than to mere information. On this basis, Article 7 of the original version of the Chilean Neuroprotection Bill proposed that the collection of brain data would require explicit "opt-in" authorisation and that neural

data could not be transferred and used commercially. In the current version of the Bill the prohibition on commercialisation of neural data has been dropped, however free, prior, explicit, informed and specific consent for neural data sharing is still required. Article 7 of the Bill also requires that all (medical or non-medical) neurotechnologies "must be previously registered by the Public Health Institute for their use in humans". This will facilitate oversight by the Chilean Public Health Institute who have statutory powers to sanction and prosecute those in violation of the Act.

Mr. Greely noted that the American Constitution does not contain provisions to protect against potential challenges raised by neurotechnologies. However, he also cautioned against the premature introduction of new human neuro-rights and pointed out that many of the predictions made 20 years ago in relation to the power and application of neurotechnologies has yet to come to pass. This is largely because our tools are not yet sophisticated enough and, perhaps even more pertinently, the human brain is more complicated than first envisaged. He pointed out that the more measured progress in this field acts as a cautionary tale for not getting ahead of the science and try to regulate something which has yet to come to pass. That is not to see that new neuro-rights may be required at some time in the future. Mr. Greely noted that everything we do is brain-based, we are constantly changing other's brains, (e.g., by engaging in conversation which results in a physical change, like the formation of a memory that can be recalled). Distinguishing between what changes we are making to the brain, with or without neurotechnologies is very difficult, this is why we must be very cautious with developing legislation.

During the panel discussion, the difficulty of reaching an international consensus regarding the need and form of new neuro-rights was acknowledged, and it was suggested that it may be wiser to focus on soft law instruments at this point in time. The question was also raised of when is the right moment to intervene with legal instruments (so to avoid inhibition of innovation). Soft law can be useful and in the interim, but it is important to prepare for hard law by having discussions such as these. As a prelude to the introduction of neuro-rights we need to understand first how society will understand and implement these technologies and how to protect uses themselves. There was a general consensus that there was an ethical responsibility to ensure that the priority for applications in the neurotechnology field should be oriented towards alleviating human suffering. It was noted that there is an asymmetry in the legal corpus around medical (highly regulated) versus non-medical (lacking regulation) uses of novel technologies. This is problematic as it ignores the potential for dual use of neurotechnologies. Several contributors acknowledged that "neurotechnology" can be an all-encompassing word which covers very different forms of technology and realities. There was also agreement that there were specific advantages to placing the governance of neurotechnology within

the existing human right framework as these provide concrete protections for individuals and facilitate discussion of fundamental conceptual questions. Discussing international treaties was also deemed important as it was seen as a mechanism for convergence which could inform development of national legislation which could accommodate a diversity of cultural perspectives. Other bottom-up forms of governance (e.g., principles) were also discussed. There was agreement that we must innovate in a socially responsible and human-centric manner. This means that technology must be developed with, in, and for society. Horizon scanning coupled with public discourse (which accurately captures the potential and limitations of neurotechnologies) was deemed an essential precursor to elaboration of specific neuro-rights.

CONCLUSIONS AND FUTURE STEPS

Intervening effectively and safely in the human brain using neurotechnologies offers significant potential to secure important social goods, first and foremost alleviating human suffering due to neurological and mental health conditions. However, these novel technologies also raise significant ethical and legal challenges both within the biomedical field and beyond. Applications of neurotechnologies raise ethical questions regarding autonomy, equality, discrimination and privacy. Non-medical applications generally can be categorised as those related predominantly to recording/sensing and to a lesser extent influencing brain activity. Currently capacities of most consumer-grade technologies are at a relatively crude state of development, but more sophisticated technologies can be anticipated in the years ahead. At this juncture neuro-devices (direct-to-consumer) in the non-medical field have little potential to traverse mental privacy, but it is noteworthy that there is minimal regulatory oversight of non-medical neuro-devices which are available directly to consumers.

Given the unique characteristics of the brain and its link to the mind which defines our humanity through thoughts, emotions, consciousness, it has been suggested by some that to effectively govern innovation in the field of neuroscience, new neuro-rights are required. In the report commissioned by the Council of Europe Committee on Bioethics which foregrounded the current seminar Ienca defines neuro-rights as *"the ethical, legal, social, or natural principles of freedom or entitlement related to a person's cerebral and mental domain; that is, the fundamental normative rules for the protection and preservation of the human brain and mind"*. While specific "neuro"-rights may well be important in the future, it may be premature to embark upon creation of such rights at this juncture. There is no clear consensus regarding the conceptual-normative boundaries and terminology of neurorights. Divergences exist in relation to how these rights are interpreted, named, and conceptually articulated. Moreover, there is a risk that elaboration of new rights could lead to accusations of rights inflation which poses the risk of undermining existing fundamental rights and thus far, proposed "neuro-rights" could be encompassed under many existing human rights instruments and articles.

A more productive avenue of exploration in terms of governing innovation and application of neurotechnologies within and beyond the field of biomedicine may be a form of multi-level governance. This would include a process of interpreting and applying existing rights

or indeed adding to the scope and content of existing rights to ensure adequate protection of individuals using neurotechnologies for medical, social or economic purposes. It is recognised that human rights law is aligned vertically and not horizontally in that it places duties on states to respect the rights of individuals but creates few private duties. While it may be difficult to legally enforce human rights against private actors, the rights framework confers a moral responsibility on both public and private actors to develop and apply neurotechnologies in a manner in keeping with corporate responsibility and due diligence. Multi-level governance should aim at creating a normative eco-system in which innovations and applications of neurotechnologies are value-based and inclusive. While recognising that the formal and material requirements of law are distinct from ethical principles, multi-level governance can include codes of conduct that integrate ethical principles and recourse to ethical committees or to trustees are examples of integration of ethics in legal tools. For “soft tools” to be effective there is a requirement to foster interactions between funders and developers of neurotechnologies and legal/ethical professionals, so that governance and protections can develop in tandem with innovations in the field. As part of multi-level governance, public discourse is vital in order that innovation is steered in a direction which aligns with public goals and values.

In thinking about future activities, it is important to ensure coherence and collaboration across international organisations with an interest in this field. Principle 5 of the OECD Recommendation on Neurotechnology advocates for the promotion of open communication across expert communities and with the public. The goal of principle 5 is to promote neurotechnology literacy and the exchange of information and knowledge as well as calls for multi-stakeholder dialogues and deliberation to ensure diverse inputs into decision-making processes, public policy and governance. In line with Article 28 of the Oviedo Convention, the Council of Europe Committee on Bioethics in its Strategic Action Plan has underscored the importance of fostering a dialogue between the public, scientists, and policy makers to ascertain the most appropriate governance models needed for biomedical technologies and their applications. To this end the Committee has recently published a Guide to Public Debate on Human Rights and Biomedicine. There is an opportunity to explore future opportunities to work with OECD to raise public awareness around neurotechnologies and to facilitate an inclusive societal deliberation on how such technologies should be deployed and regulated. In further support of a multi-level governance approach and building on the report commissioned by the Committee on Bioethics on Common Human Rights Challenges Raised by Different Applications of neurotechnologies, the Committee could seek to develop an Interpretative Guide to Adapting Existing Human Rights to neurotechnologies to guarantee that the protection of human rights is a guiding consideration throughout the entire process of research, development, and application.