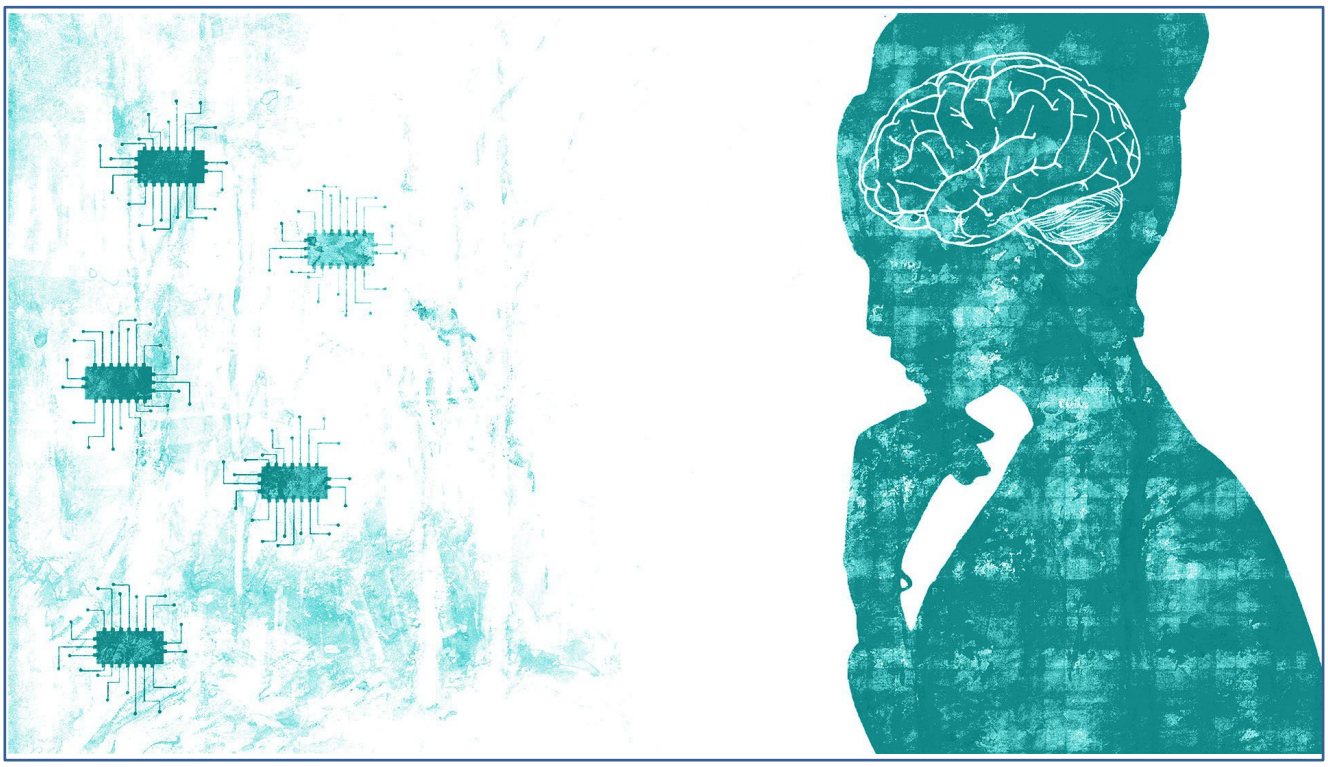
Ethics Strategy for International Collaboration on the Integration of Neuroethics and Neuroscience (D9.4 – SGA3)



Integration of neuroethics and neuroscience

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Description in GA:	Drawing from an overview of the main challenges faced by the different international brain initiatives when integrating neuroethics and neuroscience, this deliverable will propose a general strategy and methodology (result of collaborative work) that fosters an ethically sustainable and conceptually sound research infrastructure (EBRAINS) and can be used by other Brain projects.
Abstract:	This deliverable presents an overview of HBP's integration efforts and of our work with the IBI in identifying roadblocks to the integration of neuroethics and neuroscience. Drawing from this, the deliverable provides general recommendations for fostering ethically sound brain research and research infrastructures.
Keywords:	Neuroethics, neuroscience, integration, international collaboration, international brain initiatives
Target Users/Readers:	Consortium members, neuroscientists, neuroethicists, EBRAINS users, EC, policy makers, funding agents

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1. Introduction

The development of neuroscience and the availability of big data have not only contributed to a richer understanding of the brain, but also created significant opportunities for the development of diverse neurotechnologies that might impact societies in different ways. Awareness of the promises and the challenges that brain research, its outputs, and applications might present prompted the HBP to take a number of steps to identify and address neuroethical concerns within the responsible research and innovation (RRI) framework promoted by the European Commission. Since the beginning of the Project, the focus has been both on integrating neuroethics and philosophy as part of the scientific research [1] [2] [3] and on how the research and the technology it enables can be developed and practically implemented responsibly [4].

The HBP's proactive approach to addressing ethical and societal considerations has contributed to the international discussions on how to carry out neuroethical reflection in general and has also led to a productive international collaboration with the different existing Brain Initiatives. In this Deliverable, we describe these collaborative activities and preliminary results, discussing in particular the integration of neuroethics and neuroscience.

Why is the integration of neuroethics and neuroscience important? The answer requires a few comments on how we understand scientific excellence. Indeed, rather than considering it just in terms of epistemic progress and solely revealed by peer review, we understand scientific excellence as a combination of many factors, including the social acceptability, desirability, and trustworthiness of the relevant research. If accepted, this socially and ethically inclusive understanding of scientific excellence gives support to the view that the kind of reflection undertaken by neuroethics and the integration of neuroethics and neuroscience are crucial, since they are mutually supportive. An ethically and socially reflective science benefits and enhances society and ethical and social reflection benefits and enhances science.

Drawing on both our experience in identifying and addressing ethical issues within the HBP and on several joint activities organised by the International Brain Initiative (IBI) Global Neuroethics Working Group during 2020-2021, in this Deliverable we do two things. In the first part, we present an overview of HBP's integration efforts and of our work with the IBI in identifying roadblocks to the integration of neuroethics and neuroscience. [5] The second part comprises some general recommendations for fostering ethically sound brain research and research infrastructures.

Before we proceed, however, a clarification on our use of the term 'strategy' in the title of this document is in order. Indeed, considering the nimbleness of science, the evolving nature of the ethical and social issues it raises, and the relevance of particularities and of historical, economic, and cultural contexts, our main goal here is not to provide a specific set of rules, granular action-plans, or concrete ways to foster ethically and societally aware neuroscientific research. Of course, we are aware that there are some ethical and social concerns that continue to permeate research and also that, despite diversity, it may be possible to find some cultural convergence around a few important issues and mitigation strategies: when that is the case, we try to be as specific as possible. However, our main goal is to provide general recommendations that can be used as a starting point by different research communities and stakeholders to a) guide future conversations on the ethical

[1] Salles, A., Evers, K. & Farisco, M. Neuroethics and Philosophy in Responsible Research and Innovation: The Case of the Human Brain Project. Neuroethics 12, 201–211 (2018). https://doi.org/10.1007/s12152-018-9372-9

[2] Salles et al (2019) The Human Brain Project: Responsible Brain Research for the Benefit of Society. Neuron 101:3 DOI 10.1016/j.neuron.2019.01.005

[3] Evers, K (2016) The contribution of neuroethics to international brain research initiatives Nature Reviews Neuroscience 18(1) DOI:10.1038/nrn.2016.143

[4] Bernd Carsten Stahl, Simisola Akintoye, Lise Bitsch, Berit Bringedal, Damian Eke, Michele Farisco, Karin Grasenick, Manuel Guerrero, William Knight, Tonii Leach, Sven Nyholm, George Ogoh, Achim Rosemann, Arleen Salles, Julia Trattnig & Inga Ulnicane (2021) From Responsible Research and Innovation to responsibility by design, Journal of Responsible Innovation,8:2,175-198,DOI: 10.1080/23299460.2021.1955613

[5] Special thanks to Karen S. Rommelfanger, co-chair of the IBI Global Neuroethics Workgroup until 2023 for sharing many of her insights on our joint activities.

and social issues raised by neuroscientific research and applications, b) facilitate meaningful engagement with and reflection on the identified neuroethics issues within diverse communities and c) provide some general recommendations on appropriate tools/approaches to neuroethics integration in neuroscience projects minding the fact that the best approach must be nimble, i.e. sensitive to the ethical and social issues as they emerge.

The findings offered here contribute to HBP's Outcome 6 'Thanks to the HBP's contributions and leading role envisaged in PO7, the International Brain Initiative will deliver solid neuroethics guidance to neuroscience projects in the world; in particular, regarding the ethics of large neuroscience research infrastructures.' Indeed, we expect this document to be an important building block for a comprehensive international strategy beyond particular research projects and the International Brain Initiative. It is also intended to facilitate reflection on the integration of ethical and societal considerations in research infrastructures such as EBRAINS. Importantly, this Deliverable complements Deliverable D9.5 'Implementing RRI in EBRAINS: website, RRI toolkit, and capacity building activities'.

Deliverable D9.4 is expected to find receptive audiences in the Human Brain Project, EBRAINS, the European Commission, the International Brain Initiative, and in all those invested in the ethical quality of brain research and its potential and actual applications.

2. PART I

2.1 Neuroethics in the HBP

How ethical considerations and neuroscience have been integrated and, in particular, how neuroethics has been conceived and operationalised in the HBP can be partly understood in the context of how neuroethics is integrated both within scientific research itself[6] and within the framework of Responsible Research and Innovation (RRI).[7]

RRI is generally understood as an interactive process that engages multiple stakeholders, including citizens, who must be mutually and jointly responsive and work toward the ethical acceptability of both the research and its products. The EC defines RRI as 'an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation' and makes explicit the importance of six key policy areas: public engagement, gender, open access, ethical issues (understood as research ethics), education, and governance. RRI calls for aligning science and technology with societal needs and for addressing the legal, ethical, and social dimensions of research and innovation by focusing not just on outcomes, but also on the process itself as well as the values that inform the trajectory of the scientific work and that feed into the research agenda itself.

The HBP's Ethics and Society Subproject (SP12) adopted the RRI AREA framework (anticipation, reflection, engagement, and action) developed by the UK Engineering and Physical Sciences Research Council and based on the work of authors[8], who argue that RRI requires anticipation, reflection, deliberation, and responsiveness. Ethical considerations are expected to be built in at the development stage, ensuring that all the HBP research complies with the relevant legal and ethical regulations, that is, making sure that the research has obtained appropriate ethical approval and is conducted according to approved ethical guidelines, but also, importantly, by preparing for the future through the examination of potential scenarios (so as to minimise risks and guide the direction of research) and engagement with the relevant stakeholders in an open and interactive way.[9] Ethical action is, thus, guided by anticipation and engagement, but also by careful neuroethical reflection. The latter is intended to open up a different, productive space for carrying out theoretical analysis and to offer distinctive and possibly complementary approaches to the issues investigated by empirical science, examining key neuroscientific and philosophical notions (e.g. consciousness, or human versus artificial intelligence), and enhancing HBP research itself. Indeed, the HBP's Ethics and Society team attempted to enrich the RRI approach by bringing a number of diverse research traditions, skills, and practices to it and carrying out different types of analysis, including philosophical analysis, to contribute to further refinement of the very concept of RRI in brain research.[10]

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[6] Evers, K (2016) The contribution of neuroethics to international brain research initiatives Nature Reviews Neuroscience 18(1) DOI:10.1038/nrn.2016.143

[7] Salles, A., Evers, K. & Farisco, M. Neuroethics and Philosophy in Responsible Research and Innovation: The Case of the Human Brain Project. Neuroethics12, 201–211 (2018). https://doi.org/10.1007/s12152-018-9372-9 Salles A. Farisco M (2020) Of Ethical Frameworks and Neuroethics in Big Neuroscience Projects: a View from the HBP. AJOB Neuroscience target article. AJOB Neuroscience 11:3 167-175.

[8] Stilgoe, J., R. Owen, and P. Macnaghten. 2013. Developing a framework for responsible innovation. Research Policy 42: 1568–1580; Owen, R., P. Macnaghten, and J. Stilgoe. 2012. Responsible research and innovation: From science in society to science for society, with society. Science and Public Policy 39: 751–760, Owen, R., J. Stilgoe, P. Macnaghten, M. Gorman, E. Fisher, and D. Guston. 2013. A framework for responsible innovation. In Responsible Innovation, ed. R. Owen, J. Bessant, and M. Chichester Heintz. UK: John Wiley & Son.

[9] Stahl, B., S. Rainey, and M. Shaw. 2016. Managing ethics in the HBP: A reflective and dialogical approach. AJOB Neurosci 7 (1): 20–24

[10] Ibid.

In the last stage of the Project what was initially the Ethics & Society SP12 became the Responsible Research and Innovation Work Package 9 (WP9). Wholly devoted to research on and implementation of RRI in the Project and future research infrastructure, WP9 continued to have a strong neuroethics and philosophy component including not only our Task, Neuroethics and Engagement (T9.3), but also diverse ethics and neuroethics Tasks embedded in scientific WP1, WP2, and WP3. We provide a more granular description of neuroethics in the HBP below.

2.1.1 Neuroethics conceptualisation and methodology in the HBP

The philosophy and neuroethics research in the HBP have been largely devoted to *fundamental neuroethics* (a concept introduced by Evers).[11] Three core features, related to topic and to methodology, distinguish fundamental neuroethics from other neuroethical approaches: it pursues *foundational* analyses within a *multidisciplinary* research domain using an *interdisciplinary* methodology. Topically, fundamental neuroethics pursues basic research and analyses foundational concepts and methods used in the neuroscientific investigations of notions like, for example, simulation, identity, or consciousness. These analyses necessarily involve both empirical scrutiny of the science in question and philosophical analyses of the concepts involved. Fundamental neuroethics is accordingly multidisciplinary because it involves elements from different disciplines, including the natural and social sciences as well as philosophy of science, philosophy of language, philosophy of mind, and moral philosophy. In other words, fundamental neuroethics cannot be subsumed under any particular classical discipline. Methodologically, fundamental neuroethics is ipso facto interdisciplinary because it combines a variety of methods, e.g. empirical and conceptual methods related to the different disciplines.

These features distinguish fundamental neuroethics from other approaches to neuroethics as described below. Yet, since all forms of neuroethics require some foundational analyses in order to be viable, it could also be said that all forms of neuroethics must somehow involve, or be developed on, a basis of fundamental neuroethics (whether or not they use this label).[12]

Ultimately, in our work we have identified three prevalent methodological approaches within the field.[13]

A “neurobioethical” approach: applies ethical theory and reasoning to practical issues arising from neuroscientific research and its applications -for example, the ethics of expanding applications of deep brain stimulation, the ethics of cognitive neuroenhancement- and to those issues raised by public communication of neuroscientific findings and their impact -such as how to manage societal expectations and control ‘neuro-hype’.

An ‘empirical neuroethical’ approach uses empirical data to inform theoretical issues such as the brain structures subserving moral reasoning, or the relation between personal identity and brain identity, the nature of consciousness and related ethical implications, and practical issues such as who qualifies as a conscious or moral agent.

A ‘conceptual neuroethics’ approach: at its most basic it entails the recognition that the full range of issues raised by neuroscience cannot be adequately dealt with without a) a careful conceptual clarification of the relevant notions (behaviour, intelligence, digital twin, consciousness) and b)

[11] Evers, K. 2007. Towards a philosophy for neuroethics. An informed materialist view of the brain might help to develop theoretical frameworks for applied neuroethics. EMBO Reports 8 Spec No:S48-S51. https://doi.org/10.1038/sj.embor.7401014; Evers, K. 2009. Quand la matière s'éveille. Paris: Éditions Odile Jacob.

[12] Farisco, M., Evers, K. & Salles, A. On the Contribution of Neuroethics to the Ethics and Regulation of Artificial Intelligence. Neuroethics 15, 4 (2022). https://doi.org/10.1007/s12152-022-09484-0

[13] Evers K. Salles A. Farisco M. Theoretical framing of neuroethics: the need for a conceptual approach. In Debates about Neuroethics. Racine E Aspler J. eds. Springer, 2017; Salles A. Evers K. Social Neuroscience and Neuroethics: A Fruitful Synergy. In: Ibanez A, Sedeno, L., Garcia, A., editor. Social Neuroscience and Social Science: The Missing Link: Springer, 2017; Salles et al, note 6, Salles A. Evers K. Farisco M. (2019) The Need for a Conceptual Expansion of Neuroethics AJOB Neuroscience 10:3 DOI 10.1080/21507740.1632972

examination and clarification of the often implicitly assumed connection between neuroscientific findings and the examination of basic human concerns, from the nature of consciousness and morality to the existence of free will, among others.

2.1.2 Neuroethics embeddedness in the HBP

The creation of diverse structures and mechanisms to implement neuroethical and societal considerations in the scientific research and its applications facilitated compliance and promoted reflection on actual and potential ethical issues during the initial phases of the HBP. However, in order to achieve a more granular understanding of some of the questions raised and further enhance the integration of neuroethics and philosophy within neuroscience, the HBP decided to do more. In addition to Project-wide working groups (created during SGA1 and SGA2) that target specific issues of concerns (see Section 2.1.3), starting in SGA3, the Ethics and Society team decided to embed neuroethics and ethics Tasks in the scientific Work Packages (WP1, WP2 and WP3).

In the HBP, we have used the notion "embedded" to refer to the practice of collaborative interdisciplinary work characterised by diverse methodologies and approaches in order to identify and address the philosophical and ethical issues raised by the research. In what follows, we provide an overview of this embedded work in the different scientific Work Packages.

Research in WP1 has focused on the capacity to personalise brain network models, which, by construction, generate functional brain signals linkable to behavioural indicators such as cognitive performance e.g. intelligence, and memory capacity. Promising as the outcomes of the research are, personalised brain modelling raises important conceptual and philosophical issues and has a number of societal and ethical implications. These have been addressed by the embedded neuroethics Task 'Societal and ethical impact and implications of personalized brain modelling' where philosophers and neuroscientists engaged in productive discussions of the key issues, among them, the provision of the conceptual clarity necessary for WP1 to adequately construct and communicate research on personalised brain models or virtual/digital twins of individual brains; and suggestions on how to address and communicate the main ethical and social implications. In the process, the team analysed the concepts of 'Virtual Brain' and 'Digital Twin of the Brain' in terms of relations to the physical twin; assessed their adequacy and usefulness, and elucidated the relationship between environmental versus cerebral structural/functional variability: links between brain signals and behaviour; variability and identity; individualisation and personalisation in brain models, and identified clinical applications of building Virtual/Digital Twins of brains, articulating their ethical and societal implications, and promoting responsible embedding and use of the relevant findings in society

Although initially limited to just a few researchers/tasks, the collaboration of philosophers and scientists in WP1 (including the WP-leader) has been fruitful and constructive. In addition to relevant joint reports, it resulted in scientific articles both published (Evers & Arleen 2021[14], Evers 2020[15]) and under review, and the organisation of diverse activities and lectures in international workshops and conferences such as 'BrainComp Workshop on Brain Inspired Computing' (2022), 'EITN Workshop: Virtual Brains & Digital Twins: A Tentative Roadmap - Neuroethical perspectives' (2022), and 'American Philosophical Association Pacific Meeting' (2021).

Work in WP2 aims to advance our understanding of the structural and functional brain underpinnings of cognitive and conscious processes in the brain through cognitive, computational, theoretical, clinical, and philosophical analyses. Neuroethics and philosophy are particularly relevant to research on consciousness for both theoretical (e.g. clarification of the meaning of consciousness and of its necessary and sufficient conditions) and practical (e.g. the ethical need for improving the clinical detection of conscious activity in patients with brain damage) reasons. Importantly, this has been

[14] Evers, Kathinka, and Arleen Salles, "Epistemic Challenges of Digital Twins & Virtual Brains: Perspectives from Fundamental Neuroethics," SCIO: Revista De Filosofía, No. 21, 2021, pp. 27–53 (P3011).
[15] Evers, Kathinka, "The Culture-Bound Brain: Epigenetic Proaction Revisited," TheoriaVol. 86, No. 6, 2020, pp. 783–800 (P2591).

recognised by researchers/tasks is in WP2 where philosophical analyses are broadly appreciated and ethics is considered crucial to the scientific enterprise.

The embedded neuroethics Task 'Neuroethics and Philosophy of Cognition and Consciousness' has collaborated extensively with researchers from WP2 on three main topics: a reflection about the conditions for a theory of consciousness to be accounted as such; a reflection about the definition of consciousness and the identification of its markers, that is features that justify the attribution of consciousness to other agents (human, non-human animals, and machines); a reflection about the ethical implications of research on consciousness, including its potential contribution to ameliorate the condition of patients with different grades of coma and their caregivers.

Research in WP3 seeks to advance our understanding of human cognition by emulating the architecture and operation of the brain. In practice, this entails the design of brain- inspired functional cognitive architectures. In this WP, the aim of the embedded ethics Task 'Application of RRI to AI and bio-inspired modelling' is 'to further develop the reflection (including researcher awareness and engagement activities) about AI in order to define feasible conceptual and ethical tools for assessing the consistency of AI-related work by HBP with the RRI framework to ensure that societal benefits aimed for are achieved' (description in the Grant Agreement). Neuroethical and philosophical analysis also played a significant role in this Task.

The Task has benefited from contributions by different partners in the humanities and the social sciences. Team members have focused on a number of topics, from the potential issues emerging from the actionability of European and other relevant AI guidelines and from the international transfer of AI technology to conceptual analysis of the ethics of AIbio-inspired modelling, and neuro-robotics applications. These analyses and reflections have resulted in several publications focusing on the criteria for the ethical analysis of AI and the connection between neuroethics and the ethics and regulation of AI (Farisco et al 2022[16] ;Farisco et al 2020[17], Salles et al 2020[18]). As the Task progressed, the work was enriched by enhanced collaboration with other colleagues and tasks within the WP, which led to productive internal meetings and a collaborative interdisciplinary paper on the ethics of brain-inspired AI co-authored by several researchers in WP3.

Finally, as noted before, this Deliverable is the product of the work of the embedded neuroethics Task in WP9. Our Task, 'Neuroethics and Engagement', has undertaken conceptual and normative reflection on the ethical, social, and philosophical issues that drive and arise from brain research and from the design and implementation of neuroscientific research within and beyond the HBP. An important component of our Task has been the continued collaboration with existing international brain initiatives (including but not limited to engagement activities) and systematic work on culture, as shown in Deliverable D9.3, this Deliverable D9.4, and diverse scientific publications and dissemination activities (see below).

As is to be expected, not all embedded groups had the same experiences, nor were they all perceived in the same way by their science colleagues. Importantly, however, embeddedness allowed for a better interdisciplinary understanding of the issues and a more focused and granular approach to managing them.

2.1.3 Project-wide working groups: The case of Dual Use of Concern and Misuse

In addition to the embedded Tasks, the HBP has developed other forms of interdisciplinary collaboration between Ethics and Society team and neuroscientists. The goal in this last phase has been to continue strengthening them. One such collaborative format is project-wide working groups

[16] Farisco, Michele, Kathinka Evers, and Arleen Salles, "On the Contribution of Neuroethics to the Ethics and Regulation of Artificial Intelligence," Neuroethics Vol. 15, No. 1, 2022 (P3225).
[17] Farisco, Michele, Kathinka Evers, and Arleen Salles, "Towards Establishing Criteria for the Ethical Analysis of Artificial Intelligence," Science and Engineering Ethics Vol. 26, No. 5, 2020, pp. 2413–2425 (P2577).
[18] Salles, Arleen, Kathinka Evers, and Michele Farisco, "Anthropomorphism in Ai," AJOB Neuroscience Vol. 11, No. 2, 2020, pp. 88–95 (P2506).

on specific topics, in particular: dual use, data governance and diversity. Here we focus on the HBP's work on dual use.

Dual use is an ethical issue that has special importance in the European Union's political, historical, and regulatory context. Like any project funded by the EU Framework Programme, the HBP had to comply with the legal requirement that all its research should have an exclusive focus on civil applications and that work on military applications is not allowed. That sets the HBP apart from other brain initiatives and a lot of neuroscience research, some of which even receives some funding for defence research[19].

In contrast, the HBP not only complied with the legal requirement but developed a broader approach to dual use, going beyond the traditional civil-military dichotomy. The HBP Ethics and Society team undertook wide-ranging research and engagement activities within and beyond the Project to develop a document, an Opinion on Responsible Dual Use [20]. The Opinion argues for the need to consider a broader range of potential concerns that neuroscience research can raise in political, security, intelligence, business, and other domains. To follow up on the Opinion, the HBP has established a Project-wide Dual Use Working Group that brings together members from all Work Packages. The group provides a safe space for raising and discussing any potential concerns and ways of discussing them. Meeting regularly and developing common vocabulary and understandings are important for having an ongoing discussion of emerging topics and questions. This includes discussing topics emerging not only within the HBP but also the relevance of political developments for the HBP. For example, the group has discussed potential implications for the HBP and EBRAINS in relation to an emerging topic of covert foreign interference in research and innovation that has gained broader relevance in the EU and in several countries in Europe and beyond.

Combining research and practice, this group collaborates with scientists and other stakeholders in the HBP and beyond. In the HBP, it works closely with the Ethics Rapporteur programme - another Project-wide group - facilitating reflection on potential dual use of concern and misuse in different Work Packages. Collaboration with the HBP Education programme is crucial for organising workshops for students and early career researchers. These workshops reveal that many early career researchers are very interested not only in dual use but also in broader ethical and social issues. However, they often note that their education has not included training on these issues and that these considerations are also not taken into account in career and academic reward systems.[21] These collaborations help to develop a network for mutual support and learning.

The approach to dual use of concern and misuse developed in the HBP has attracted interest beyond the HBP with regular invitations to present this approach to other researchers and stakeholders, including for another Future and Emerging Technologies (FET) project and for the European Commission.

2.1.4 Neuroethics and Engagement in the HBP

Citizen -and multi-disciplinary engagement and dialogue (or 'public engagement' as an umbrella term) are considered essential activities to RRI, as they help build a better understanding of societal needs and values within science, and thus have the potential to steer scientific development towards societally desirable and acceptable outcomes. Accordingly, the Ethics and Society team has taken the creation of spaces for ethical and societal reflection with relevant stakeholders as key to unveiling and managing the issues.

[19] Ulnicane, Inga. 2020. "Governance of Dual Use Research in the EU: The Case of Neuroscience." In Emerging Security Technologies and EU Governance: Actors, Practices and Processes, edited by Antonio Calcara, Raluca Csernatoni, and Chantal Lavalée, 177-191. Routledge. https://doi.org/10.4324/9780429351846-12

[20] Aicardi C, Bitsch L, Bådum, NB, Datta Burton S, Evers K, Farisco M et al. Opinion on 'Responsible Dual Use': Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology. 2018. 20 p. https://doi.org/10.5281/zenodo.4588600

[21] Ulnicane I. Mahfoud T. Salles A. (2022) Experimentation, learning, and dialogue: an RRI-inspired approach to dual-use of concern, Journal of Responsible Innovation, DOI: 10.1080/23299460.2022.2094071

To that end, and in order to better identify and address the broad legal, ethical, philosophical, and social issues raised by the research, the HBP's engagement team created, organised, and participated in a broad range of activities engaging European citizens, as well as experts in law, ethics, sociology, and the humanities with brain science researchers, computer scientists, and engineers. Topics covered include citizens values and expectations for data governance and privacy in research projects[22] , citizen and stakeholder views on dual use of research for civilian purposes[23], citizens views on acceptable use of AI[24] and multi-stakeholder identification of major AI challenges and best mechanisms for mitigating risks[25] and citizens' views on personalised disease signatures and data governance in research infrastructures[26].

The HBP approach to public engagement is based on theories on deliberative democracy and the idea that well-informed citizens and experts reach rational decisions through dialogue and listening to each other's experiences, knowledge, and perspectives.

Identifying, defining, and describing issues for building engagement activities have taken different forms over the years. Since late 2019, the engagement team have made a concerted effort to advance neuroethics engagement. The explicit focus on combining neuroethics and engagement in SGA3 emerged from activities under the IBI neuroethics working group (see Section 2.2). During 2019, the IBI neuroethics working group organised a number of activities intended to explore the potential role of public engagement in neuroethics. In particular, a workshop in Uppsala, Sweden, and the Global Neuroethics Summit in Daegu partly inspired the HBP engagement team to focus on how to strategically engage diverse publics with neuroethical issues.

One of the goals of neuroethics is to draw attention to the value-laden nature of neuroscientific activities. As noted in D9.3, neuroscientific activities reflect the society and culture in which they take place and are shaped by culturally based assumptions about what a good life is and what are the relevant activities leading to a good and meaningful life. Public engagement, understood as an exercise in mutual learning about the experiences, needs and views of others, can help research better understand citizen experiences, knowledge, and values and how neuroscientific research priorities and outputs could address their needs or fit into diverse social, cultural and human practices. The strength of the HBP's approach to public engagement has exactly been its insistence on multidirectional dialogue and deliberation.

In exploring an approach to neuroethics engagement, the HBP engagement team had three main key starting points:

- The five main neuroethical questions identified by the International Brain Initiative Neuroethics working group (see Section 2.2).
- Setting up a working group with researchers and staff across the HBP, and consulting with them on neuroethical topics of priority for the HBP and EBRAINS for public engagement exercises
- Methodological questions on the potential of combining qualitative data from day long workshops with dialogue between citizens and experts with quantitative data from digitally facilitated citizen meetings (see Section 2.3.2)

The intent was to anchor urgent neuroethical questions with the most pressing concerns of the HBP and EBRAINS. The above ultimately led to a thematic focus on personalised disease signatures and data governance in research infrastructures. Theme and methodological approach are further explained in Section 2.3.2.

[22] Living up to privacy and informed consent in the Human Brain Project: https://tekno.dk/app/uploads/2021/03/HBP_Privacy_informed-consent_Policy-Options_01.pdf
[23] https://tekno.dk/app/uploads/2021/03/Nr.-7-Dealing-with-dual-use-of-HBP-research-The-citizens-perspective-1.pdf
[24] https://sos-ch-dk-2.exo.io/public-website-production/filer_public/18/92/18924584-3beb-4592-b45c-f71a24340e61/d1231_d771_d112_sga2_m23_accepted_201006.pdf
[25] https://tekno.dk/app/uploads/2021/03/AI360_Newsletter..pdf
[26] https://tekno.dk/app/uploads/2023/02/HBP-Citizen-views-on-data-sharing.pdf

2.1.5 Some Challenges to Neuroethics Integration in the HBP

Even when the HBP has taken important steps to embed neuroethics in the scientific Work Packages and to address ethical issues in an anticipatory way, some practical roadblocks remain. One such roadblock is that some researchers still believe that our work focuses mostly on ethics compliance.[27] It is true that ethics compliance plays a key role in any type of responsible research: researchers are justified in worrying about complying with all the relevant regulations and guidelines. However, to consider ethical reflection as limited to compliance rests on a) a misunderstanding of both the nature of science itself (which is inescapably value laden and entangled with social, political, and cultural contexts) and b) the impact of neuroscientific research on society in general. Furthermore, it is clear that there might be a number of ethical issues (quite obviously in the case of emerging issues) raised by the research that fall outside actual regulatory frameworks and might call for rethinking common ethical approaches. Finally, understanding neuroethics solely in terms of compliance leads to a negative and misleading view of the discipline as potentially inhibiting research. The fact is that grappling with the issues raised by brain research and its applications in diverse domains requires moving away from simplification and to viewing neuroethics as a mode of inquiry that broadens and deepens a type of reflection that is necessary for a productive normative debate. Thus, the key role played by the neuroethical approach embraced by the HBP Ethics and Society group, which conceives of the discipline as a mode of knowledge seeking and solution creating inquiry beyond compliance with soft and hard regulation.

A second obstacle we have faced is the prevalence of certain beliefs that are sometimes taken for granted in the scientific community, for example, about the alleged value neutrality of science. This view often leads to viewing neuroethics as limited to a service role: achieving societal approval of neuroscience and its products. Of course, promoting a more socially situated understanding of neuroscience is both conceptually and practically challenging. It requires a change in the way scientists usually see their own work as a research activity setting its own priorities and following its own rules and a change in the way scientists do their job, i.e. moving from mono-disciplinary or intra-scientific multidisciplinarity (often requiring the juxtaposition of insights from several similar disciplines) to interdisciplinarity (that requires integration of insights from diverse disciplines), involving also extra-scientific expertise for inspiring scientific investigation and assessing its connection with society.

The embedded neuroethics Tasks in the scientific WPs have been better equipped to address some of the issues raised by collaborative work. However, the difficulties raised by interdisciplinary work in general continues to be a topic of debate within the social sciences, and our interdisciplinary experiences in the domain of neuroscience give support to the idea that there is room for further reflection about how to improve structures, strategies, and practices of interdisciplinary collaboration between neuroscience and neuroethics (and the social sciences and the humanities in general) beyond embeddedness.[28]

2.2 IBI Global Neuroethics Working Group

The Global Neuroethics Workgroup (GNWG) of the International Brain Initiative was formed in 2016 in anticipation of the formation of the International Brain Initiative. Its goal was to act as a convener and ideas incubator, advancing responsible, ethical, and culturally aware neuroscientific practices in general by bringing together the insights gained from neuroethics research and activities in the different brain initiatives. During the first five years, the group was constituted of representatives from the HBP, US BRAIN Initiative, Japan's Brain/Minds, and the Korean Brain Initiative and

[27] Bernd Carsten Stahl, Simisola Akintoye, Lise Bitsch, Berit Bringedal, Damian Eke, Michele Farisco, Karin Grasenick, Manuel Guerrero, William Knight, Tonii Leach, Sven Nyholm, George Ogoh, Achim Rosemann, Arleen Salles, Julia Trattnig & Inga Ulnicane (2021) From Responsible Research and Innovation to responsibility by design, Journal of Responsible Innovation, 8:2, 175-198, DOI: 10.1080/23299460.2021.1955613
[28] Ibid.

consultants from the Canadian Brain Research Strategy, Australian Brain Alliance, and the China Brain Project.

Since its creation, the IBI Global Neuroethics Work Group has been active in convening a number of meetings to address specific topics, and this has resulted in diverse peer-reviewed publications and reports.[29] Of particular interest for its impact on some HBP activities is the GNWG group's first output, a publication in Neuron identifying five key neuroethics questions and additional subquestions that can be usefully addressed across all national-level brain initiatives. The formulation of the questions was informed by extensive and intensive conversations with representatives from the different brain initiatives and they were developed to be adapted and informed by the cultural values of diverse communities and their respective local frameworks. They included issues such as: what are the ethical standards of biological material and data collection, and how do local standards compare with those of global collaborators?; what is the moral significance of engineered neural circuitry?; how can brain interventions affect autonomy?; what is the potential impact of a biological model or neuroscientific account of disease on individuals, communities, and societies?; and what are the possible uses and misuses of neuroscience?. Importantly, as noted in Sections 2.1.4 and 2.3.2, these questions were taken as a starting point of several public engagement exercises and activities in the HBP.

2.2.1 IBI Global Neuroethics Working Group and the Challenge of Integration

In 2020, the IBI GNWG (Global Neuroethics Working Group) set about strategising toward neuroethics integration with neuroscience, specifically in the Big Brain Projects. This aim was partly driven by awareness that despite the apparent widespread recognition of the term 'neuroethics' in the neuroscientific milieu and the generally agreed upon view that research and its products must benefit society, much remains to be done in terms of neuroethics 'capacity building and integration in the neuroscience community' (IBI GNWG).

Within the different international brain initiatives, the status and operationalisation of neuroethics is uneven. In some of these projects, neuroethics is at an earlier stage of development and the concern is fundamental ethics compliance. In contrast, in brain projects such as the HBP there are highly developed ethics and neuroethics strategies, structures, mechanisms, and engagement activities intended to address the ethical, social, philosophical, and regulatory issues raised by brain research beyond compliance. Still, as noted before, even in the best cases challenges to integration remain and they must be identified and addressed to have a truly effective integration of neuroethics and neuroscience.

Accordingly, from December 2020 to December 2021 the IBI GNWG undertook several activities to a) map out the existing situation regarding neuroethics integration, b) gain understanding of several stakeholders' perspectives on the need for integration, and c) identify challenges to integration.

The first activity consisted in a cross-IBI meeting intended to increase understanding of goals and undertakings of the GNWG within the IBI, including promoting a clearer understanding of IBI's priorities and goals and identification of synergies and commonalities. Among the issues discussed were the challenges raised by interdisciplinarity and cultural diversity.

For the last activity, the IBI Neuroethics working group partnered with IEEE (Institute for Electrical and Electronic Engineers) to organise the BI-IEEE Brain Workshop 'Integrating Neuroethics in Neural Engineering Efforts- Initial Workshop with International Partners'. This workshop engaged with different publics: neuroscientists, neuroethicists, and neuro-engineers to discuss the promises of

[29] Global Neuroethics Summit Delegates, Rommelfanger KS, Jeong SJ, Ema A, Fukushi T, Kasai K, Ramos KM, Salles A, Singh I. Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives. Neuron. 2018 Oct 10;100(1):19-36. doi: 10.1016/j.neuron.2018.09.021. PMID: 30308169; Salles et al note 2; Salles & Farisco note 9, Das J, Forlini C, Porcello DM, Rommelfanger KS, Salles A and Global Neuroethics Summit Delegates (2022) Neuroscience is ready for neuroethics engagement. Front. Commun. 7:909964. doi: 10.3389/fcomm.2022.909964. For complete list see https://globalneuroethicssummit.com/resources/

emerging neurotechnologies and the issues they raise when deploying them in the clinical, wellness, legal, gaming and work domains.

Between these two shared events, the IBI GNWG organised targeted interdisciplinary activities in the form of webinars and round table discussions including experts from differing disciplines and geographic areas. Each of those activities was preceded by preparatory internal IBI Neuroethics meetings where key topics for discussion were selected and intended outcomes determined. In some instances, pre-meeting surveys (intended to set the stage for the topics discussed during the meeting) were sent to participants. Each activity was, in turn, followed by internal IBI Neuroethics meetings to assess insights gained and debate potential tentative strategies for addressing the questions and issues raised by the different experts.

Some of the key questions discussed include: what are the preferred and working definitions of neuroethics in the different brain projects and are they consistent with those prevalent in the field? What is the value of neuroethics and what its role? With which stakeholders has the field engaged the most? Who is represented and who is not represented within the field? Can neuroethics partner with neuroscience to optimise both research and outputs while keeping the necessary critical distance? Can neuroethics keep up with the pace of emerging neurotechnologies? And, importantly, what counts as integration? Why is integration desirable? How does integration work in a variety of contexts? How should integration be implemented (beyond real-time interdisciplinary formal and informal collaborations?)

The activities outlined above buttress and enhance existing literature on neuroethics and its relation to neuroscience. Importantly, they made evident that even if there is agreement in that better integration of neuroethics and neuroscience is needed, such integration requires previous identification of roadblocks. Based on the activities, the group identified three general persistent challenges to integration of neuroethics and neuroscience: conceptual, valorative, and structural.

Internationally, several understandings of neuroethics coexist. Neuroethics is seen variously as the ‘ethics police’ (compliance), as neuroscience’s cheerleader, as critical examination, as a type of philosophical reflection, as ‘just another applied ethics’, and often as a combination of some of the above. The lack of agreement regarding how to understand the field is not without impact: the multiplicity of understandings affects the field’s receptivity by different publics and creates significant challenges for productive collaboration.

In turn, the lack of clarity regarding the role of neuroethics in the scientific enterprise is related to the fact that there appears to be no consensus on how to understand ‘scientific excellence’. As noted in the introduction, if scientific excellence is understood as rooted on epistemic virtues and solely captured by peer review or viewed in terms of the breakthroughs it produces in particular areas of knowledge and practice, the role and value proposition of neuroethics as a multi and interdisciplinary field that addresses ELSI and philosophical issues, at least initially, becomes less evident than if scientific excellence is seen as necessarily encompassing social and ethical (that is, non epistemic) considerations as well.

How one understands the nature, role, and value of neuroethics is important for a number for reasons. Such understanding impacts the public’s support for its integration with neuroscience and alters diverse communities’ view of whether neuroethics should be seen as a key player in scientific research or not. This is not a minor point: understanding neuroethical reflection and implementation as valuable and crucial to the scientific enterprise is likely to lead to attracting funding and/or devoting available resources (financial and human) to developing it. Unsurprisingly in our activities with diverse stakeholders, the lack of financial and time resources as significant challenges to integration came up consistently. Moreover, how one understands neuroethics and its value impacts people’s view on whether the scientific agenda should be shaped by neuroethical considerations, whether scientists should spend time on identifying and addressing the ethical and social issues raised by their research, and whether the development of education programs and more meaningful communication between neuroethicists and neuroscientists is needed.

The joint work with the different international brain initiatives enabled a rich discussion on many of these topics. It led to a clearer understanding of common challenges in ensuring the development of responsible neuroscience research of the relevant issues and reaffirmed the need for continuous collaborative work to identify and address those challenges and to co-create ways to implement

solutions. Some preliminary steps identified and discussed by the group include the importance of raising awareness regarding the social situatedness of neuroscience and the role played by non-epistemic values in the neuroscientific enterprise, the inclusion of a neuroethics component in public and private sectors' grants, the creation of neuroethics exchange programs to embed neuroethicists in different labs or neurotechnology companies (seen as particularly productive as a strategy to build interdisciplinary trust), fostering further reflection on neuroethics as culturally situated, and enhancing multidirectional engagement with diverse communities, among others.

2.2.2 A Note on Culture

In the section above we referred to the importance of cultural situatedness. Indeed, it seems that if the goal is integration of neuroethics and neuroscience, attention must be given to cultural contexts.

From the beginning, the IBI GNWG made efforts to highlight the significance of recognising cultural diversity and its impact in neuroscience and its products. The first joint scientific publication by the group noted that cultural diversity affects both scientific research itself and its social and ethical acceptability and warned against minimising the consequences of cultural misunderstandings in the scientific enterprise.[30]. Indeed, gaps in cultural awareness and cultural engagement may lead to unproductive collaborations and to limiting the use and potential benefits of neuroscientific research and applications. Moreover, culturally aware neuroethical reflection is instrumental in raising and framing issues and co-creating adequate mechanisms and solutions to manage them. Because culture informs both science and how its products are deployed, any recommendation for integration of neuroethics and neuroscience must be sufficiently nimble to fully capture the issues in context[31] and, at the same time, to recognise that not all issues are articulated in the same way nor can be equally addressed in all contexts.

Aware of the need to acknowledge cultural situatedness as a starting point for any attempt to integrate neuroethics and RRI activities, in the last phase of the Project this Task (T9.3) engaged more directly with culture. Aligned with points made within more recent neuroethics discussions and those made the IBI GNWG's paper mentioned above, in Deliverable D9.3 'Analysis on cultural considerations in RRI and neuroethics'[32], we discussed the need to consider culture and cultural diversity among the factors that should be specifically considered in order to: a) enrich and integrate our understanding of the relevant ethical and societal questions, b) promote a sound and ethically sustainable knowledge production, c) enhance the interfacing of neuroscience and society, d) maximise societal impact of and benefit from neuroscience and e) create adequate governance structures.[33]

2.3 EBRAINS

So far, we have discussed neuroethics integration efforts and challenges in the context of the HBP and our collaborative activities with the different international Brain Initiatives. During the last phase of the HBP, however, we were tasked with considering not just neuroethics in projects but also in Projects' outcomes. Since the HBP's main legacy is a research infrastructure, EBRAINS, we have devoted resources to reflect on how to integrate RRI, including neuroethical reflection, into EBRAINS to make it socially acceptable, morally desirable, and sustainable. Next, we provide an account of the role that collaboration with international partners beyond the HBP played in shaping the discussion as well as some engagement activities informed by such collaborations.

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[30] Global Neuroethics Summit Delegates, Rommelfanger KS, Jeong SJ, Ema A, Fukushi T, Kasai K, Ramos KM, Salles A, Singh I. Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives. Neuron. 2018 Oct 10;100(1):19-36. doi: 10.1016/j.neuron.2018.09.021. PMID: 30308169.
[31] Ibid.
[32] Analysis on cultural considerations in RRI and neuroethics
[33] In this Deliverable, we understand cultural diversity as referring to the differences among people, including socio-cultural background, ethnic and geographic identity.

2.3.1 International Collaboration for the EBRAINS Ethics and Society Vision

The RRI EBRAINS Task force (TF) was created to facilitate the transition of the HBP into EBRAINS while upholding the Responsible Research and Innovation (RRI) (including neuroethics) framework into the new research infrastructure. Chaired by the AISBL, the TF was constituted by HBP representatives from both neuroscience and RRI areas as well as from HBP/EBRAINS leadership.

The TF's mandate was to assist in the development of practical steps to implement RRI in EBRAINS. This included the identification of the appropriate structures, instruments, and activities and the integration of responsibility beyond ethical and legal compliance. In accordance with its Terms of Reference, issues such as Data controllership, Data Governance, Ethics compliance, Inclusive and Anticipatory governance, Neuroethical Reflection and Neuroethics Service, and Equality, Diversity, and Inclusion should be integrated into the EBRAINS governance structure. The TF has met monthly since its creation.

The first output of the Task Force was the Ethics & Society Vision (E&S vision) for EBRAINS, which required the engagement and insights of several internal stakeholders. An early version of the document was introduced internally (to the HBP community) at the 2021 HBP Summit for feedback. A later version received input from a panel of international experts including representatives from academia (neuroscientists, neuroethicists, and RRI experts), civil societies, policy and philanthropic organisations (OECD, Dana Foundation), international organisations (WHO, IBI) and gender studies as well as from different geographical regions (Canada, USA, the EU, South Korea, and Japan).

A number of common neuroethical themes emerged from the Ethics & Society Vision International Consultation. Among them, there were calls for further conceptual clarification of notions used in the Vision (e.g.: inclusive gender diversity, privacy by design, value sensitive design) for more inclusiveness, for richer neuroethics engagement and deliberative involvement of societal stakeholders, for a shift to a culture of ethics within EBRAINS, and for increased clarification of the interaction of the research infrastructure with the market[34].

Accordingly, the final version of the E&S Vision added statements emphasising the importance of promoting trust in EBRAINS by furthering its societal acceptability, calling for engagement of historically marginalised groups, and for further self-reflection 'on the ethical acceptability, desirability, and sustainability of EBRAINS processes and their outcomes and products' among others.

Engaging diverse international actors has led to widening the scope of EBRAINS vision beyond the European context. Next, we provide a more detailed account on the work on engagement and its relevance to neuroethics integration in EBRAINS.

2.3.2 Neuroethics Engagement towards EBRAINS

The availability of vast amounts of health and related data is the precondition for conducting much of the research which the EBRAINS research infrastructure (RI) aspires to underpin. Thus, collecting and curating these data is central to the aspirations of EBRAINS, along with providing the tools for conducting research on this data and the community to do it with. That these data are central to EBRAINS value proposition is clear from the description of EBRAINS on its webpage: 'EBRAINS is a new digital research infrastructure […] that gathers an extensive range of data and tools for brain-related research.' But this also means that EBRAINS is dependent on the acceptance of the people whose data are being curated by the RI. Thus, EBRAINS needs to understand what European citizens think about the platform and its operations, to ensure both that its operations are not counter to what the general population finds acceptable and its societal legitimacy. For this reason, the focus of the last round of public engagement activities revolved around understanding European citizens' views on what processes for collecting and sharing neurodata are acceptable, what research should

[34] Advancing a responsible, ethical vision for EBRAINS https://ebrains.eu/news/advancing-a-responsible-ethical-vision-for-ebrains

and should not be conducted, as well as what safeguards should be in place to ensure ethically sound genesis, use of and adequate protection of data.

The vantage point for identifying the focus of this engagement process was the neuroethics questions identified by participants at the Global Neuroethics Summit (see Section 2.2.1).[35] These were ethical questions that participants from across the world could agree needed to be addressed in order to foster more international collaboration in neuroscience research. To narrow the scope and identify which of the questions would be more relevant to EBRAINS' long-term aspirations, an internal workshop with EBRAINS and HBP members was held. This workshop was followed up by several interviews with key stakeholders across HBP and reviews of the aspirations of what EBRAINS wants to achieve and what could constitute major roadblocks to accomplishing it. More specifically, the process centred on the neurodata collected in the EBRAINS infrastructure, particularly regarding how they are collected, how they are shared and utilised, and who gets access to them.

For the implementation of this process, the engagement team in the Danish Board of Technology developed an approach combining two different citizen engagement methodologies. One of them, the MoM (Mixing of Minds) Workshops, was specifically designed for this process while the other, GlobalSay, is a tried and true methodology. When taken together, the resulting process is known as a Mixing of Minds process. The two formats have the same focus but take slightly different approaches to uncovering citizens' thinking about these topics. In combination this approach enables a structured and informed democratic dialogue about key societal issues and develops complementary outputs.

The MoM workshops are in-person full-day events, where citizens come together with selected stakeholders from the field of the topic to discuss and exchange opinions. The MoM workshop methodology complemented the GlobalSay results in two different ways. Firstly, it is intended to generate qualitative outputs which can provide substance and reasoning. Secondly, the citizens collaborated with stakeholders like neuroscientists, representatives of CSOs (civil society organisations), NGOs or stakeholder organisations, to develop responses to challenging questions such as how to handle the ethical, legal, and practical challenges to international collaboration and data sharing. In each workshop attending citizens developed recommendations that were then further nuanced in collaboration with the stakeholders. Subsequently all the recommendations were analysed and clustered in thematic sections, which led to the development of five overarching recommendations synthesising the general recurring arguments throughout the workshops.

The GlobalSay citizen hosted meetings entail small-scale deliberative processes where any citizen can invite guests to participate in digitally facilitated discussions and answer a questionnaire from their own chosen location, thus providing a quantitative output. GlobalSay served to generate a general overview of opinions and attitudes to various aspects of international research collaboration and sharing of health data and created quantitative substantiation of the recommendations developed in the MoM workshops.

The Mixing of Minds process was implemented in 6 European countries, namely Denmark, England, Germany, Hungary, Italy and Spain, and it ran from October 2021 to August 2022. In total, the process comprised 6 full-day workshops, 66 small-scale meetings, more than 450 citizens and 25 stakeholders across all countries.

The end result is a report presenting the 5 recommendations from the MoM workshops substantiated by the statistical analyses of the GlobalSay meetings. The recommendations focus on what European citizens think should be implemented when establishing cross-European data collection and sharing practices and infrastructures. The report ends with presenting what the role of different actors should be in realising the recommendations from the citizens. The results report is available as OP9.8: 'Citizen's views on neuroethical issues and societal benefit'.[36] A more detailed description of

[35] Global Neuroethics Summit Delegates, Rommelfanger KS, Jeong SJ, Ema A, Fukushi T, Kasai K, Ramos KM, Salles A, Singh I. Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives. Neuron. 2018 Oct 10;100(1):19-36. doi: 10.1016/j.neuron.2018.09.021. PMID: 30308169.
[36] https://tekno.dk/app/uploads/2023/02/HBP-Citizen-views-on-data-sharing.pdf

the Mixing of Minds Process itself can be found in OP9.5: 'Methodological concept for citizen engagement useful as a foundation for global citizen engagement'[37].

3. PART II

3.1 Neuroethics and Integration: Pending Issues?

Since 2002, the field of neuroethics has focused on identifying and reflecting on and managing the ethical, social, and philosophical issues raised by brain research. As shown in this Deliverable, more recently, the emphasis has been put on how to integrate this type of ethical reflection with neuroscience and its innovations and on identifying challengers to such integration. Furthermore, a number of organisations such as the Organization for Economic Cooperation and Development (OECD[38], UNESCO[39], the Council of Europe[40], the UK's Horizon Regulatory Council[41], have issued recommendations to optimise governance of emerging technologies or, as in the case of IEEE[42]) are in the process of developing a neuroethics frameworks intended to assess the ethical, philosophical, social, and legal issues raised by neuroscience and its applications in diverse domains even if actual implementation is not part of the mandate. [43] Still and despite existing efforts, there are pending issues such as: what is the best way to integrate neuroethics and neuroscience and its innovations? Are guidelines really needed? If so, do we need new guidelines or are existing ones enough? and how to efficiently operationalize guidelines in different contexts?

The issue of whether guidelines and recommendations are good enough for smooth integration, whether new guidelines are needed, and whether existing recommendations such as the OECD's are to be preferred are topics that are receiving significant attention as of late and that promise to continue to be part of the discussion for a while. Interestingly, what we see at present is that while the need for integration is widely recognised, the value proposition of articulating new guidelines is in question. What remains clear, however, is the need for further exploration of how to best implement integration mechanisms.

Our work in the HBP (a Project characterised by its cultural and disciplinary diversity) and our joint research with our international colleagues beyond the HBP show that even if not in the form of formal guidelines, there are some common concerns that must inform any attempt to practically integrate ethical and societal considerations with neuroscientific research and innovations. And in this sense, general recommendations, if sufficiently nimble, can play a key role. Thus, below we present the following recommendations that emanated from our work in this Project and from our interactions with representatives from the existing brain initiatives and other international audiences.

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[37] https://tekno.dk/app/uploads/2023/05/HBP_SGA3_OP9.5_Citizen_Engagement_Methodology.pdf

[38] OECD Recommendation on Responsible Innovation in Neurotechnology https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm

[39] Report of the International Bioethics Committee of UNESCO (IBC) on the ethical issues of neurotechnology https://unesdoc.unesco.org/ark:/48223/pf0000378724

40 Strategic action plan on human rights and technologies in biomedicine (2020 - 2025) https://rm.coe.int/strategic-action-plan-final-e/1680a2c5d2

[41] Regulatory Horizons Council: the regulation of neurotechnology https://www.gov.uk/government/publications/regulatory-horizons-council-the-regulation-of-neurotechnology

[42] IEEE neuroethics framework https://brain.ieee.org/publications/neuroethics-framework/addressing-the-ethical-legal-social-cultural-implications-of-neurotechnology/

[43] O'Shaughnessy, Matthew and Johnson, Walter G. and Johnson, Walter G. and Tournas, Lucille and Rozell, Christopher and Rommelfanger, Karen, Neuroethics guidance documents: Principles, analysis, and implementation strategies (February 15, 2022). Available at SSRN: https://ssrn.com/abstract=4035992

3.2 General recommendations for integrating Neuroethics and Neuroscience

1) Make sure that the conditions for effective integration of neuroethics and neuroscience are present. This importantly includes:
   a) Ensuring the commitment of leadership to the integration of neuroethics and neuroscience
   b) Ensuring the existence of sustainable resources (human and financial)
   c) Ensuring openness and transparency in the creation of partnerships and the search for revenue and funding opportunities, with special attention to the possibility of conflict of interest
2) Promote a culture of ethics in science that includes:
   a) Awareness of the socio-ethical dimension of neuroscience and of the social impact of emerging neurotechnologies
   b) Recognition that ethical research and innovation require more than compliance
   c) Attention to cultural aspects that inform science and its outputs

This can be facilitated by the development of culturally sensitive capacity building programs and the creation of multiple activities (at all career levels) to raise awareness of the interaction between neuroscience and neuroethics.

3) Create the relevant communication and engagement strategies: seamless communication with diverse communities plays a significant role in integration, but such communication must be sensitive to the needs and possibilities of each community (scientific community, communities of patients, industry). This entails:
   a) Developing engagement mechanisms to reach out to all stakeholders
   b) Inclusive interdisciplinary dialogue informed by the insights of communication and engagement experts and training in good practices
   c) Conceptually clear research and communication. Clear language and conceptual analysis are key to building any productive approach to integrating ethical and societal considerations with neuroscience and its applications and to communicating and connecting with diverse publics.
4) Create 'safe spaces' for raising and discussing ethical and social concerns freely, creating networks of support and mutual learning and promoting an ongoing dialogue between ethicists and neuroscientists that allows to develop shared vocabulary and understandings.
5) Combine research and practice on neuroethical issues where research provides input into practice, while practice indicates new questions for research.
6) Use and experiment with diverse formats of interdisciplinary collaboration between neuroscientists and ethicists including embedded tasks, project-wide working groups, ad hoc task forces etc.
7) Create clear governance structures and standard operating procedures that support recommendations above as articulated in D9.2[44] Toolkit on equality in governance structures, procedures and implementation (www.edi-toolkit.org).
8) Create a monitoring system to periodically assess the implementation of the recommendations and accommodate emerging challenges.

[44] https://sos-ch-dk-2.exo.io/public-website-production-2022/filer_public/e8/d8/e8d84de2-ea57-4fd1-82de-6bdb78b0403a/d92_d76_sga3_m18_accepted_220520.pdf

3.3 General recommendations for integrating Neuroethics in Research Infrastructures

As noted above, EBRAINS is the main legacy of the HBP. It is being developed to become a lasting European digital Research Infrastructure (RI). One challenge of research infrastructures in general is how they can integrate neuroethical considerations and principles and practices of responsible innovation.

In general, attributing value to neuroethics within the neuroscientific enterprise promotes integration of the field by attracting funding and human resources. As noted in the sections above, however, neuroethics is not a unified field: the HBP has used a rich conceptualisation of neuroethics that encompasses not only practical and empirical approaches but conceptual analysis as well. A rich conceptualisation of neuroethics is key not just to enhance and integrate understanding of the relevant ethical and societal questions. It plays a key role in the promotion of a sound and ethically sustainable knowledge production. In a research infrastructure, going beyond regulatory and ethical compliance to offer practically relevant analyses of key scientific concepts (reliability, validity) is key.

Although much remains to be done in terms of the operationalisation of the adequate mechanisms to integrate neuroethics in a research infrastructure such as EBRAINS, drawing from our work in the HBP, in the RRI EBRAINS Task Force, and our research with the different international Brain Initiatives, we recommend the following:

1) Ensure that the leadership and management are committed to integration of neuroethics and neuroscience
2) Ensure a sustainable budget that is not project-based but rather an integral part of the RI
3) Develop a neuroethics structure with a clear independent mandate to function as a high-level service. This neuroethics structure can offer the following:
    a) Neuroethics tutorials and training material, i.e. in the same way that EBRAINS will include tutorials, or documentation, for how to use the various infrastructure components. collaboration to ensure access to all potential users
    b) Help desk (offering internal and external services) in a similar model to the BBMRI-ERIC ELSI help desk[45]
    c) Establish engagement mechanisms to reach out to sister projects or infrastructures, civil society organisations, to support proactive exploration and dialogue with society with the aim of implementing consideration of these needs into research and brain science technologies
    d) Establish a set of criteria for the expertise needed to offer neuroethics services

4. Final Reflections

One of the main lessons arising out of our work in neuroethics and neuroscience in the HBP and jointly with the different international brain initiatives is the need to promote lasting awareness of the importance of integrating ethical and societal considerations in brain research and innovations. This requires seeing neuroscience and neuroethics (richly understood) as equal partners jointly working to construct and improve knowledge and identify and manage ethical and societal impacts. Our collaborative work with the different international brain initiatives and our multiple interactions with other international audiences emphasised that to avoid just paying lip service to integration, it is key to first identify the ethical, social, cultural, and conceptual roadblocks to its success. Only

[45] BBMRI-ERIC ELSI HELPDESK https://www.bbmri-eric.eu/elsi/helpdesk/

then can we create and enhance mechanisms that enable more ethically robust neuroscientific research and applications.

In this Deliverable, we provided an overview of our work towards integration within the HBP and beyond it, describing also our sustained collaboration with the International Brain Initiative Global Neuroethics Working Group. This is an important and timely topic, being discussed globally at present. We expect this Deliverable to contribute to the ongoing dialogue within and beyond the HBP and EBRAINS. The reflection over appropriate strategies, whether more guidelines are needed or whether the focus should be put on harmonising existing ones, and the issue of how to implement guidelines in different contexts will benefit from being as inclusive and internationally informed as possible, giving a significant role not just to neuroscientists, social scientists and humanists but also to innovators, policymakers, patients' representatives and the public at large in their different contexts in order to co-create and ultimately implement the necessary solutions.