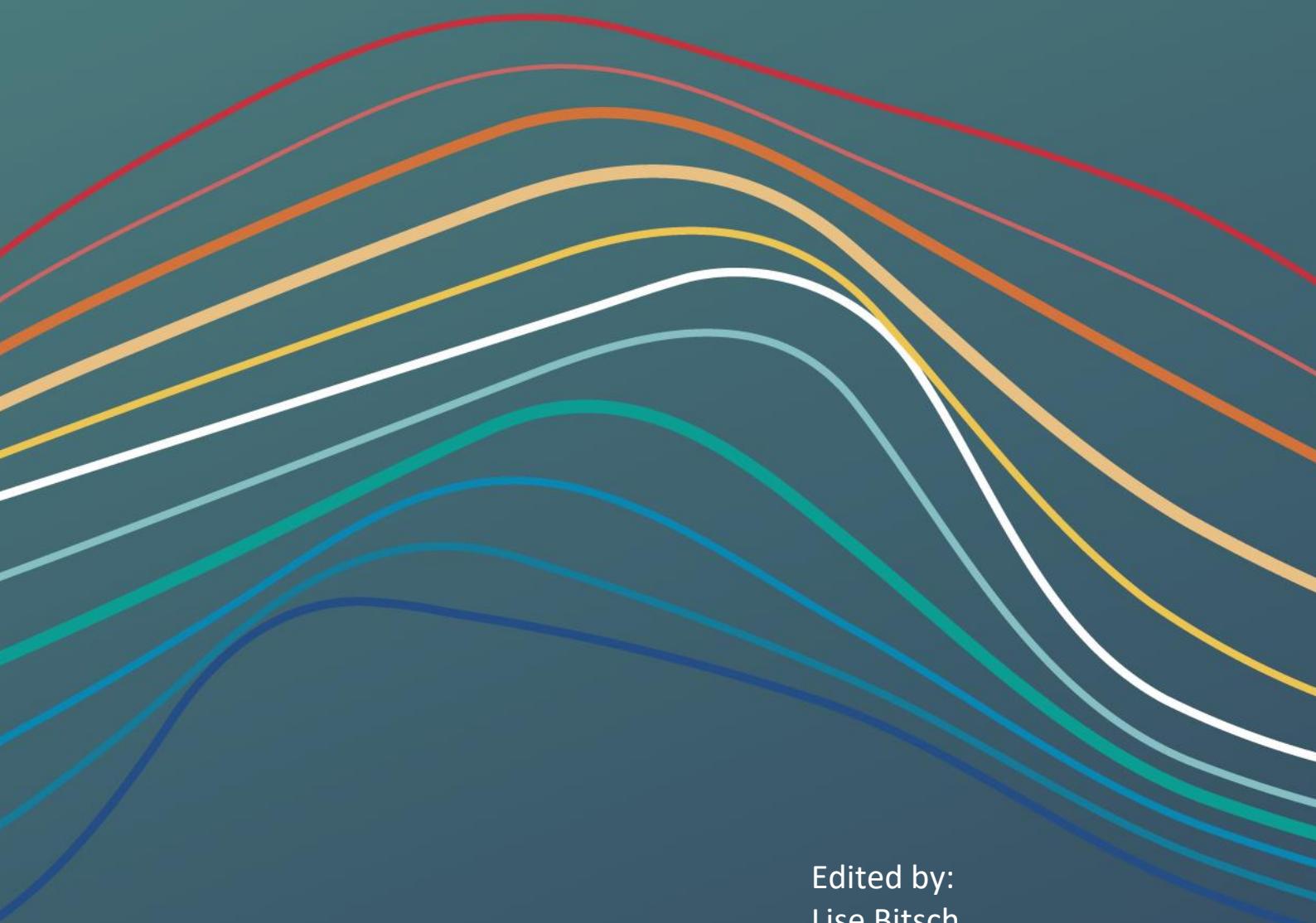


Ethics and Society in Brain Research

Implementing Responsible Research and Innovation (RRI) in
the Human Brain Project (HBP)



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Preface

When the Human Brain Project (HBP) was in its earliest planning stages, the dominant culture of natural science was such that the inclusion of research in the humanities and social sciences in the project may to many have seemed like a distant goal. Scientific communities were still strongly influenced by the old idea that ethical and social concerns were not part of scientists' responsibilities but belonged elsewhere, for others to deal with and for others to fund.

Yet a group of prominent people from distinct fields – natural and social sciences, philosophy, and ethics – proposed precisely that inclusion at the first HBP Ethics & Society planning meeting held at Collège de France, Paris, in 2011, chaired by Jean-Pierre Changeux. So, we should note that, importantly, the idea of including ethical and social considerations did not only come from the humanities but was also proposed and developed by neuroscientists.

In what would become a highly fruitful collaboration, we, the undersigned, became the first leaders of HBP Ethics & Society activities: Jean-Pierre Changeux (Neuroscience) and Kathinka Evers (Philosophy & Neuroethics). In joint efforts with the larger group, we developed and secured the place for Ethics & Society in the HBP. Space does not allow us to mention all who helped to achieve this goal, but some would also become central in the subsequent shaping of HBP's Ethics & Society activities, e.g., Nikolas Rose (leader of the HBP Foresight Lab and Social Science Research), Bernd Carsten Stahl (Ethics Director and leader of Ethics Management) and Lars Klüver (leader of Public Engagement and Deputy Lead of Ethics & Society).

Thanks to these pioneering efforts, the humanities and social sciences, philosophy, and ethics, became firmly rooted in the Human Brain Project's research core, and provided with an adequate share of the budget. In this respect, the HBP differs from all other large national or international brain projects that more narrowly include ethics as a regulatory activity, not as research.

The underlying ideas and values that prompted this strong position of what first became known as the Ethics & Society Subproject (SP12), based on the recognition that science does not operate in a social void, and that it is not normatively neutral. To be responsibly pursued, research in neuroscience with its focus on our most intimate organ, the brain, that is the seat of our identity, personality, thoughts, and feelings, must take the broader social and cultural contexts into account. Both in terms of addressing how social and cultural structures may shape the developing brain, and in terms of bringing to light how social and cultural values shape research plans, interpretations, and applications.

Notably, it was deemed crucial to anticipate and identify potential ethical and social concerns at an early stage by producing scenarios of potential developments and implications, and feed these back to the HBP researchers to build capacity to adapt to differing uncertain futures; to evaluate the impact of HBP outcomes on society and the individual; to examine the conceptual and ethical consequences of new knowledge of the brain; to establish constructive dialogue with European citizens and a range of stakeholder communities; to help develop ethical and social awareness within the entire consortium; to ensure conformity of HBP activities with legal and ethical standards and regulations – to inspire ethical policy beyond compliance; and to contribute to shaping research activities in the directions of societal values and needs.

Naturally, this can only be achieved through deep interdisciplinary collaborations pursued with mutual respect and collegiality. Establishing such collaborations, both within the Ethics & Society group and beyond, with the rest of the HBP, was therefore our first goal that we, in our capacities as leaders of HBP Ethics & Society, worked towards from our complementary neuroscientific and philosophical perspectives.



Together with our HBP colleagues we built a basis upon which Responsible Research and Innovation (RRI) – with its four pillars: anticipation, reflection, engagement, and action – could fruitfully be analysed and applied. In the end, our broad and varied collaborations became so successful that many of the Ethics & Society activities became embedded as research tasks ((neuro)ethics and philosophy), and support tasks for the development of the HBP and EBRAINS (Inclusive community building, co-creation and engagement, ethics support, dual use and data governance) alongside a work package devoted to RRI to ensure its legacy in the HBP and the EU research infrastructure EBRAINS, and to coordinate ethics and RRI activities across the HBP. This work was led by Lise Bitsch and Arleen Salles, who put together the present anthology.

The HBP Ethics & Society activities have been extensive and diverse. The present anthology gives insight into some of our work – it is by no means intended as a complete presentation. It is written for a general audience to provide, what we hope is, more easy access, to the work of our colleagues in the HBP over the years. The collection also includes contributions from colleagues outside of the HBP, offering external perspectives. We hope that our putative reader may find something of interest herein, and that it might be a source of inspiration for others in our fields.

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Introduction

Attention to ethical and social issues were part of the Human Brain Project's work from the very beginning in 2013. Accordingly, a group of HBP researchers from the social sciences and the humanities created several structures and mechanisms and used various conceptual and empirical methods to develop activities and to identify, reflect upon, and manage the ethical and social issues raised by brain research, its outputs, and applications. In particular, the project embraced the AREA framework¹ (Anticipation, Reflection, Engagement, and Action).

As is to be expected, collaborative constellations naturally changed over the ten-year period of the HBP. The approaches and topics that the group addressed were informed by the evolving needs of the project, changing policy landscapes, and the input of surrounding communities.

Importantly, a major and impactful change took place as the project entered its last phase. EBRAINS, a one-of-a-kind European Brain Research Infrastructure and part of the HBP's legacy, became a central focus of the project. Subsequently, all activities in the HBP were devoted to supporting and developing the emerging research infrastructure and its organising entity, the EBRAINS AISBL. To that end, in April 2020, the HBP changed its organisation from twelve Sub-Projects (SPs) to nine Work-Packages (WPs) including a Responsible Research and Innovation WP (RRI-WP) led by us (LB and AS). The RRI Work-package was structured with one strategic task and four scientific tasks: Coordination and Management of RRI led by Lise Bitsch, Responsible Research and Innovation, led by Bernd Stahl, Neuroethics and Engagement, led by Arleen Salles, Ethics Coordination and Communication, led by Bernd Stahl, and Gender Mainstreaming and Diversity Management, led by Karin Grasenick. In this last phase of the HBP, our main objective was to make sure that the mechanisms and strategies created during the project would shape the EBRAINS RI, thus ensuring the ethical and social acceptability and desirability of its operations and research activities.

Consequently, the RRI research team undertook several activities directed at deepening understanding and reinforcing implementation of RRI in the HBP and its legacy, the research infrastructure EBRAINS². Those activities included actively embedding groups of social scientists and neuroethicists in the scientific and infrastructure work-packages³, coordinating the implementation of RRI in EBRAINS^{4 5}, continued support to the Dual Use⁶-and Data Governance working groups⁷ and the Ethics rapporteur programme⁸, developing a

¹ Read more about the AREA framework on the website of the UK Engineering and Physical Sciences Research Council (EPSRC): <https://www.ukri.org/about-us/epsrc/our-policies-and-standards/framework-for-responsible-innovation/>

² For those wishing to engage with the research output of our work, we invite you to look at our scientific booklet of publications: <https://zenodo.org/record/5521270>

³ See for example the outcome of embedded work with inclusive community building here:
<https://ebrains.eu/service/ebrains-community>

⁴ Read more about the work with an EBRAINS Ethics and Society Vision here: <https://ebrains.eu/ethics-and-society-vision/>

⁵ Read more about coordination of ethics compliance here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/ethics-coordination/>

⁶ Read more about the Dual Use Working Group here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/dual-use/>

⁷ Read more about Data Governance in the HBP here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/data-governance/>

⁸ Read more about the Ethics Rapporteur Programme here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/ethics-rapporteur-programme/>

RRI capacity-building program⁹ and training toolkits¹⁰, enhancing the understanding of legal compliance of the HBP and EBRAINS, strengthening international collaboration on (neuro) ethical strategy for collaboration on the challenging issue of neuroethics integration with neuroscience and neurotechnology¹¹, developing citizen and public engagement activities¹², and working for the proportional representation of genders at all career levels of the HBP. Furthermore, topics such as gender, diversity, and culture were put specifically in the research agenda.

With this collection of essays, we aim to present our work in an accessible format, with the ambition of sharing the research and its outputs with diverse stakeholder communities, including policymakers, civil society -and interest organisations, research, and expert communities outside our peer communities. The collection includes short essays by our HBP colleagues who describe and reflect on their work at different stages of our developmental history. In the process, they offer key findings, reflection points, and lessons learned.

Our approach to reflecting upon and implementing RRI in the project has always been enriched by dialogue and interaction with diverse publics, including non HBP communities of experts in RRI and neuroethics. Therefore, we are grateful to be able to include the views of some of our international peers¹³ who participated in our final online event, the conference “The Future of Responsible Brain Research” that took place on February 2nd 2023¹⁴.

The essays in this anthology

The collection opens with a piece by Bernd Stahl, the HBP’s ethics director. Stahl notes that while it was clear from the beginning that the Ethics and Society activities would be structured in accordance with the RRI framework, the usefulness of those activities depended on the correct identification of both short and long-term ethical and social issues raised by the research. The group took on this challenge by formulating what became the “HBP’s ethics map.” Stahl describes and analyses the ethics map noting that even though ethical and social issues change over time, the pace of change is modest. He concludes by recommending a dialogical approach to identifying and addressing ethical and social issues, one that by learning from the past is better equipped to identify future ethical and social issues with reasonable accuracy.

⁹ Find our training programme here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/ethics-society-training-resources/>

¹⁰ Find the EBRAINS Ethics and Society toolkit here: <https://ebrainsethicsandsociety.tekno.dk/> and the Equality, Diversity and Inclusion (EDI) toolkit here: <https://www.edi-toolkit.org/>

¹¹ Learn more about neuroethics in the HBP here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/neuroethics-philosophy/>

¹² Read more about the public engagement activities here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/public-engagement-foresight/>

¹³ The present collection of essays was developed specifically for the final Summit of the HBP. We expect to include more essays with perspectives from the conference in a second edition of the anthology.

¹⁴ Please read more about the conference here: <https://www.humanbrainproject.eu/en/about-hbp/news/events/5809/the-future-of-responsible-brain-research>



One important dimension of RRI is “anticipation.” The Foresight Lab at King’s College London carried out anticipatory work from the beginning of the project until 2020. In their piece, Christine Aicardi, Saheli Datta Burton, Tara Mahfoud, Michael Reinsborough, and Nikolas Rose present salient aspects of their work, describing the diverse approaches and techniques they used and the breath of issues they explored. In the HBP, anticipatory activities were designed to shape the technoscientific agenda and inform the direction of research. The authors’ close by emphasising the importance of ensuring that foresight work shapes the priorities and direction of scientific research and by highlight that more work is needed to develop models that integrate social responsibility and socially beneficial research in large research consortia.

The RRI framework makes clear that in addition to anticipation, reflection should play an important role in the integration of social and ethical considerations into the scientific enterprise. In the HBP, such reflection was not just sociological and ethical but, importantly, philosophical and neuroethical as well. Neuroethics is the topic of the piece by Kathinka Evers. In her piece, Evers explains *fundamental neuroethics*, describes its novel interdisciplinary methodology, and highlights how this foundational understanding of neuroethical reflection has impacted HBP research and practice. Evers notes that in the HBP neuroethics has aimed to do more than applied ethics work: it has worked towards co-creating knowledge opening a productive space for contributing to the understanding of HBP research itself by engaging with, examining, and clarifying the core concepts and language used by neuroscience and its resulting knowledge.

In her essay, Arleen Salles also focuses on neuroethics, but this time in relation to HBP’s sustained collaboration with neuroethics teams in existing large scale brain research initiatives. Salles describes the trajectory of the International Brain Initiative’s Global Neuroethics Workgroup and notes that this international team effort has led to a clearer understanding of common challenges in ensuring the development of responsible neuroscience research and innovation, and more awareness of the need to recognise cultural and contextual considerations. She further points to the need to pursue and continue international collaboration to identify and address emerging challenges and co-create ways to implement actionable solutions.

In his essay, Lars Klüver reflects on the ambition to support EBRAINS by building open, inclusive, and collaborative community on the emerging research infrastructure. The community building effort draws from years of experience with citizen, expert, and stakeholder engagement on issues of science and technology at the Danish Board of Technology Foundation. The goal to build, not only an infrastructure of computer and people, but also an infrastructure of people from multiple communities. People that would make up a network of multiple actors, across sectors and levels of society for facilitation and operation of a research infrastructure contributing to the achievement of important societal health goals.

Engagement and participation are a key dimension of RRI, and they have long been considered a central activity to unlock insights into the needs, values, and concerns of society related to emerging science and technology. In their essay, Sissel F. Ladegaard, Elsa Alves, Francisca Nordfalk, Nicklas Bådum and Lise Bitsch provide an account of the final round of citizen and expert engagement activities in the HBP. They describe an innovative approach to combining physical workshops with digitally mediated meeting formats on the topic of data governance and brain research. Reflecting on the outcome of the exercise, the essay draws out central values of EU citizens and suggest possible avenues for integrating these in a future EBRAINS research infrastructure.



Gender equality plays a key role within the RRI framework, and this is reflected in the research and innovation programmes of the EU. Accordingly, the HBP created a dedicated task charged with providing strategic advice, designing and coordinating gender equality measures, and furthering the integration of diversity and inclusiveness within the research. This is the topic addressed by Karin Grasenick and Pilar Flores Romero, who describe the approach used in the HBP and provide recommendations based on their experience in the project.

Another ongoing ethical issue that HBP RRI researchers addressed throughout the years was dual use and misuse. In her essay, Inga Ulnicane describes the HBP's conceptual and empirical work on dual use. She notes that the HBP has gone beyond a binary understanding of the notion of dual use (civilian vs. military) and understood the notion as including political, security, intelligence, and military uses. She also points to the role played by the RRI framework in shaping the HBP's approach to addressing dual uses of concern and misuse and provides a description of the activities of the HBP Dual Use Working group. In closing she outlines important lessons learned in the process of addressing dual use issues of concern.

Being a project with the ambition of digitalising brain research, data governance was and is an ethical and social issue that has received continued attention from the HBP in general and the RRI research team. In his essay, Damian Eke describes the data governance framework that was developed for the HBP and EBRAINS. This framework integrates attention to three aspects: people, processes, and technologies and constitutes a responsible approach to data governance – a major achievement of applying the RRI framework to building approaches to data governance.

While generally recognised as necessary, the notion of “ethical compliance” often raises some concerns, particularly as it is feared that it might lead to seeing ethics as a list of mandatory boxes that researchers fill in without much thought, or as a type of policing mechanism poised to hinder research. Will Knight takes us through the approach to ethics compliance that was developed in the HBP. The approach rests on three pillars, ‘Inquire’, ‘Engage’, ‘Educate’. Each step affords a richer conversation and promotes mutual understanding between the compliance officers and the research teams. This opens a process of ethical curiosity and learning, that sees ethics and research as partners in realising a joint goal of ethically excellent research.

In the HBP, implementing and promoting RRI has included not only raising awareness of the ethical, legal, social, philosophical, and regulatory issues raised by brain research and technology but also building capacities for identifying, reflecting upon, and managing the relevant issues. To that end, the research team created and developed an RRI capacity building programme structured around several modules. This is the topic of George Ogoh’s essay. He describes the different modules that were specially created to meet the needs of the researchers in the project, and he provides highlights of the programme as well as some lessons learned.

Members of the Ethics and Society team have produced several outputs. In addition to multiple scientific publications and diverse dissemination activities, they published documents known as Opinions. Opinions are the result of a joint effort by the members of the Ethics and Society team, who in collaboration with other HBP researchers have attempted to identify, reflect upon, and suggest possible strategies for dealing with pressing ethical issues arising from HBP. In his contribution, Achim Rosemann focuses on the Opinion “Trust and Transparency in Artificial Intelligence”. He explains the genesis of the Opinion, outlining the different activities that informed this document and the main challenges that it explored as well as providing insight into follow-up activities in HBP and EBRAINS.



During the last phase of the project, the HBP RRI team worked on ensuring the legacy of RRI in EBRAINS. A central vehicle for that work was the EBRAINS task force on RRI. Constituted by representatives from diverse fields in the project, the task force, developed an EBRAINS Ethics and Society Vision, and contributed towards the creation of an EBRAINS Ethics and Society Committee. The work of the EBRAINS RRI Task Force is the topic of the essay by Amal Matar.

The RRI framework, touched on all aspects of the team's work and shaped all our activities. Accordingly, communication and dissemination could not be delegated to a communication officer to spread the work of research to the public. As Josepine Fernow explains in her essay, in the HBP communication was understood as a joint and iterative process. As such, communication is intended to build the capacities of the researchers to consider their message and audience. Researchers must therefore be active participants in developing communication goals, messages, and enhanced understanding of the heterogeneity of audiences.

Finally, in addition to research on ethics and society by HBP researchers, the HBP has always recognised the need for an independent body of experts to advise on specific ethical, social, philosophical, and regulatory issues. The essay by Berit Bringedal, Markus Christen, and Josep Domingo-Ferrer, members of the first two ELSA/EAB committees of the HBP, describe some of the challenges surrounding the establishment of such an advisory board in the HBP, from lack of clarity regarding what their mandate was to the size and multidisciplinarity of the project. The authors provide a critical overview of some of the ethical issues unique to the HBP, and they provide lessons learned in the process of trying to address them, pointing to aspects that similar advisory committees in the future might want to consider.

Perspectives from outside the Human Brain project

The essays above illustrate some of the work carried out by the HBP RRI team in their efforts to implement a rich conception of RRI in the project. They show the extent to which the work was informed by diverse backgrounds, disciplines, interests and, importantly, the experiences gained as the team confronted challenges and developed mechanisms to address them.

Credit must also be given, however, to the work of many other experts who, while not directly involved in the HBP, have conducted foundational work in RRI and neuroethics. We are, therefore, delighted and honoured to close the collection with a few short essays by our international colleagues.

In his essay, Rene von Schomberg, an STS specialist, philosopher, and leader in Responsible Research and Innovation, makes an important point: the HBP's approach to implementing RRI has contributed to responsible brain research but its impact on responsible innovation remains to be addressed. For von Schomberg, if innovation is to be governed responsibly it is important to take some specific steps such as the provision of a transdisciplinary assessment of the quality of knowledge produced by the HBP and guiding innovation towards socially desirable goals. Von Schomberg warns against developing and embracing diverse neurotechnologies without keen knowledge of what they do to the brain. Von Schomberg ends by emphasising the need for better governance approaches informed by deliberative processes.

With the benefit of a lifelong commitment to responsible neuroscience, Professor Judy Illes, recently selected chair of the International Brain Initiative (IBI) and a prestigious neuroethicist, draws attention to four key points. First, it is important to build from the past in order to move forward; second, a strong global commitment to responsible innovation must be complemented by equally strong local, inclusive, and culturally aware engagement activities; third, it is necessary to be aware of hype and to make efforts to prevent unrealistic scenarios from distracting from crucial issues, such as ensuring good brain health and



well-being for everyone, and finally, scholars need to resist the temptation to overpromise and even overstate what ethical codes of conduct can achieve.

Karen Rommelfanger, co-chair of the IBI Global Neuroethics Workgroup until 2023 and founder of the Institute of Neuroethics, draws from her work with the US BRAIN Initiative, the IBI NWG and her neuroethics trajectory to address the issue of interdisciplinary collaboration and its role in promoting an ethically sound neuroscience. She describes three main challenges to a robust collaboration of neuroethics and neuroscience and offers a set of recommendations for overcoming them. Rommelfanger closes by acknowledging the neuroethics work in the HBP while at the same time calling for continued collaborative research and practice to produce a culture of ethics that will improve both science and society.

We hope you enjoy this collection of essays and find in them inspiration for your own work.

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The Novelty of the Familiar and the Familiarity of the Novel

A reflection of ten years of responsible innovation in the Human Brain Project

Bernd Stahl (De Montfort University)

Introduction

The Human Brain Project's (HBP) Ethics and Society Programme and its work on responsible research and innovation (RRI) have been an integral part of the HBP from its inception. One question that we consistently discussed during the lifetime of the project is: what are the ethical and social issues that are raised by the unique combination of neuroscience and computing that characterises the HBP. This question was brought up by the need to define a work plan and to ensure that we covered the most pressing issues.

This question is not confined to the HBP and plays a central role for all activities that reflect on and accompany scientific research and technical development from the perspective of social sciences and humanities disciplines. The question is exacerbated by the fact that relevant consequences and implications of such scientific and technical work may well only materialise many years or decades after the initial work has been undertaken. The question I would thus like to discuss in this short article is what can be learned from the experience of the HBP.

At the outset of the HBP we knew that ethical and social questions were going to play a role, and that there was to be a dedicated stream of research dedicated to these questions (Rose, 2014). We tried to structure our relevant activities according to the budding discourse around responsible innovation (Stilgoe et al., 2013) and responsible research and innovation (European Commission, 2013) which led to a structure that covered activities such as future and foresight research, public engagement, philosophical reflection and work with members of the consortium. This structure and the work that was undertaken under its auspices has been well described during the lifetime of the project (Salles et al., 2019).

The ethics map of the Human Brain Project (HBP)

It is nevertheless notable that all of these activities are procedural, i.e. they describe and maybe even prescribe procedures for dealing with particular issues but this approach fails to clarify what the particular issues are that the procedure should deal with. An initial suggestion that was discussed during the early days of the HBP was to create a list of the substantive issues that we expected the project to raise and to proactively develop positions on these issues. This list, internally referred to as the “laundry list” was discussed controversially for a substantial period. The main argument against this approach, which eventually prevailed, was that it would put us in a position of having to predict future ethical issues of which there potentially may be an infinity, which would have diluted our efforts for each of them to the point of irrelevance.

The failure of the laundry list approach did not make the problem go away. Encouraged by comments from the EU's ethics reviewers who continued to raise the same question, we therefore attempted to develop an “ethics map”. The following Figure 1 shows an attempt to map the ethical issues:

HBP Ethics Map

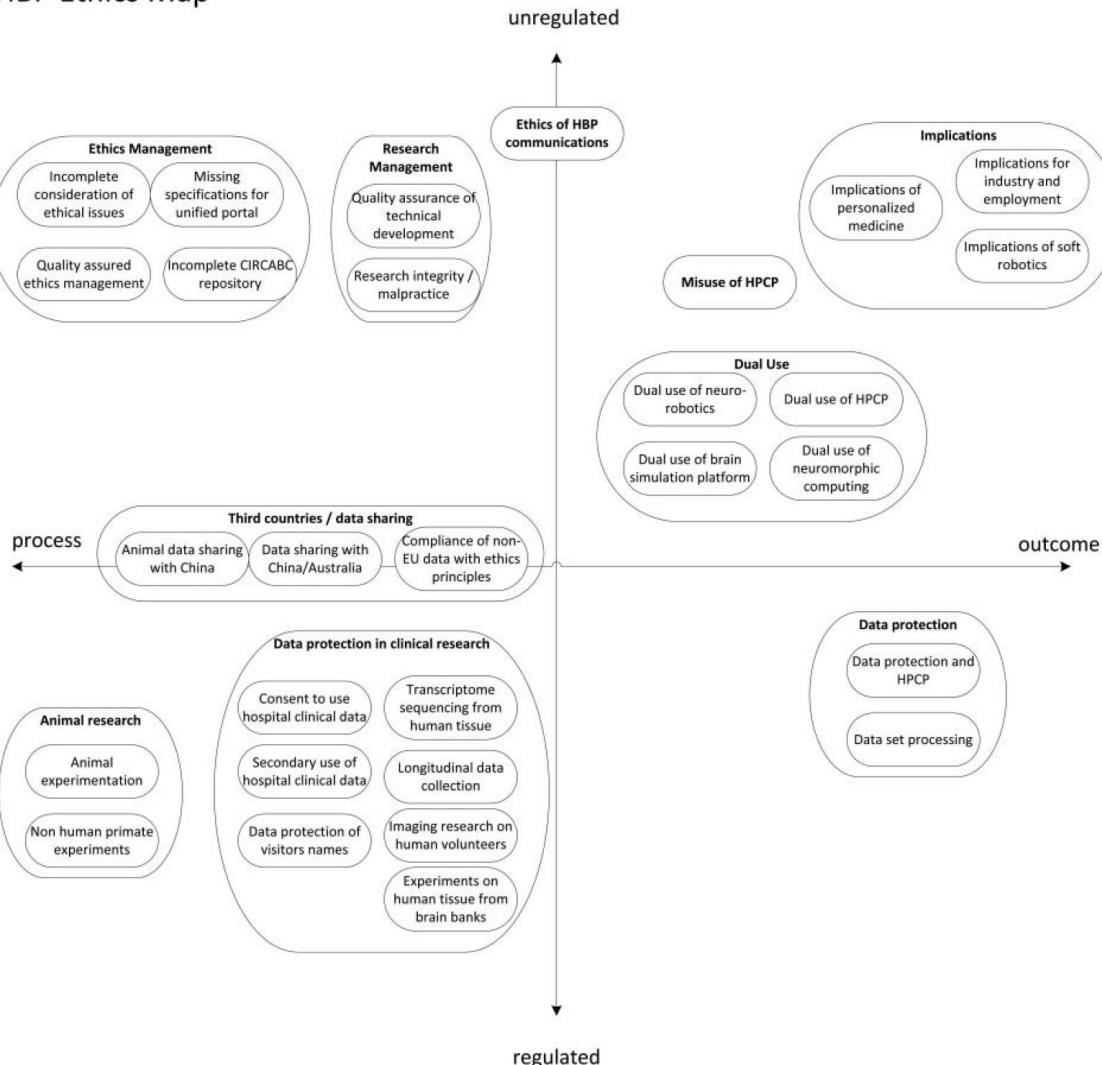


Figure 1: HBP Ethics Map, from (Stahl et al., 2016, p. 21)

The logic of this map was to look at which issues were discussed and order them according to the degree to which they were formally regulated, and to which they were oriented towards specific outcomes or processes.

Recognising the familiar in the novel

The value of revisiting this map approximately seven or eight years after it was first conceived, is that it allows for an assessment of the pace of change and the level of novelty that we encountered during the intervening years. An initial observation is that all the categories of issues in the original map are still relevant and play a role in the HBP. One can observe a shift in some of them. Notably, there is much less emphasis on animal neuroscience in the final stage of the HBP, which leads to this topic, which was initially of central importance, to be less relevant. Questions of data protection, data governance, dual use and third-party involvement remain highly relevant. Now, towards the end of the project, we have started to engage with some topics that we did not have on the radar early on, notably the ethical implications of AI.

This quick look at the HBP ethics map and changes to ethical issues demonstrates the key point I want to make in this article: ethical and social issues do change over time, but they normally do not do this at break-

neck speed. This is important for scholars from the reflective disciplines because it means that a look at past and recent issues is likely to be a good predictor for future and upcoming issues. The issues we are familiar with may develop and change emphasis and importance, but they are rarely completely novel. If we look for ethical novelty, we are well-advised to start with the familiar.

There are issues that are discipline or subject specific that we can reasonably expect to encounter. In the biomedical sciences, for example, it is reasonable to assume that questions around medical ethics, patient protection and consent will arise. Animal ethics will need to be considered where animals are involved. Where information technology is involved, it is a fair guess that questions of data protection and data governance more broadly will play a role. One can go beyond these very general terms and identify a range of relevant issues in a particular topic domain, as we have tried to do elsewhere for ethical issues arising from novel information technologies (Stahl et al., 2017) which include broader societal concerns around justice of distribution, surveillance, changes to the nature of work and market dominance of big tech.

This fact that the novelty we seek in RRI research when looking at novel technology is likely to be found in what is already familiar is a potentially important insight. It means that in future RRI projects we may start from the assumption that previously identified likely issues are a good starting point for an ethical analysis. Work like that undertaken by Brey (2012) or Wright (2011) can count as a reasonable starting point. There is no need to go back to the basics every time a new technology is introduced, or new applications are proposed.

[Bringing back the laundry list of ethical and social issues](#)

Looking back at the start of our work in the HBP, I would now argue more strongly in favour of a laundry list approach on the basis that we do not have to invent it from scratch. Rather, building on past insights into substantive ethical concerns will allow identifying most of the ones that are likely to be relevant. This should not lead to complacency, and it is clearly conceivable that new concerns arise, or new technical capabilities will lead to novel issues and concerns. In addition, all substantive ethical and social issues are context-dependent and need specific evaluation. However, while these observations suggest that an ongoing engagement through RRI remains important, I think the key insight here is, that ethical and social issues do not change rapidly. Ethical and social issues co-evolve with science and technology, and with society overall, which calls for a dialogical approach to remain engaged and aware of changes (Stahl et al., 2019). Such an approach can ensure that ethical and social issues are predicted with reasonable accuracy, at least in the short and medium term, by looking at established topics and past research.

[References](#)

- Brey, P.A.E., 2012. Anticipatory Ethics for Emerging Technologies. *NanoEthics* 6, 1–13.
<https://doi.org/10.1007/s11569-012-0141-7>
- European Commission, 2013. Options for Strengthening Responsible Research and Innovation (Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation). Publications Office of the European Union, Luxembourg.
- Rose, N., 2014. The Human Brain Project: Social and Ethical Challenges. *Neuron* 82, 1212–1215.
<https://doi.org/10.1016/j.neuron.2014.06.001>
- Salles, A., Bjaalie, J.G., Evers, K., Farisco, M., Fothergill, B.T., Guerrero, M., Maslen, H., Muller, J., Prescott, T., Stahl, B.C., Walter, H., Zilles, K., Amunts, K., 2019. The Human Brain Project: Responsible Brain Research for the Benefit of Society. *Neuron* 101, 380–384. <https://doi.org/10.1016/j.neuron.2019.01.005>
- Stahl, B.C., Akintoye, S., Fothergill, B.T., Guerrero, M., Knight, W., Ulinicane, I., 2019. Beyond Research Ethics: Dialogues in Neuro-ICT Research. *Front. Hum. Neurosci.* 13. <https://doi.org/10.3389/fnhum.2019.00105>

Stahl, B.C., Flick, C., Timmermans, J., 2017. Ethics of Emerging Information and Communication Technologies-On the implementation of RRI. *Science and Public Policy* 44, 369–381. <https://doi.org/10.1093/scipol/scw069>

Stahl, B.C., Rainey, S., Shaw, M., 2016. Managing Ethics in the HBP: A Reflective and Dialogical Approach. *AJOB Neuroscience* 7, 20–24. <https://doi.org/10.1080/21507740.2016.1138155>

Stilgoe, J., Owen, R., Macnaghten, P., 2013. Developing a framework for responsible innovation. *Research Policy* 42, 1568–1580. <https://doi.org/10.1016/j.respol.2013.05.008>

Wright, D., 2011. A framework for the ethical impact assessment of information technology. *Ethics and Information Technology* 13, 199–226. <https://doi.org/10.1007/s10676-010-9242-6>



Looking Back on the Human Brain Project's Foresight Lab 2013-2020

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Introduction

Building on earlier foresight and RRI work with technoscientific innovations such as synthetic biology (Marris and Rose, 2012), the Foresight Lab at King's College London was part of the HBP Ethics and Society division from 2013 to 2020. Its mission was to anticipate the social and ethical implications of the scientific knowledge and the technologies that may come out of the HBP. Foresight exercises are central to RRI as they aim to enable 'anticipatory' action to shape technoscientific development in desirable ways, and to assess and manage risks in a timely manner. Current approaches use two strategies, both used by the HBP Foresight Lab. The first studies the views, attitudes, and strategies of key stakeholders with empirical social scientific methods. The second uses systematic foresight techniques such as modelling, horizon scanning and scenario planning. The goals of these exercises are, first, to identify new developments and assess their potential impact over the short, medium, and longer term; second, to assess key ethical concerns such as privacy, autonomy, transparency, the appropriate balance of risks and benefits, responsibility and accountability, equity, and justice. Our foresight exercises aimed to bring out the breadth of issues that might be a concern to the wider public and specific stakeholder communities. A central objective was to feed back into the work of the HBP itself to encourage reflection among the project's researchers and managers (Aicardi, Reinsborough and Rose, 2017). Key aspects of our foresight work in the HBP are summarised below.

Data Governance, Protection and Privacy

The possibilities and hopes for computational neuroscience in generating future medicine (Rose, Aicardi and Reinsborough, 2015a), future neuroscientific understanding (Rose, Aicardi and Reinsborough, 2015b), and even future computing or robotics (Rose, Aicardi and Reinsborough, 2016) rely upon the use of large amounts of data, for example to build brain models, a collective brain atlas, or medical 'signatures' of psychiatric/neurological disease. By bringing together the researchers with stakeholders and experts the Foresight Lab was able to facilitate anticipatory discussions about ethical, societal, and practical issues of federating/sharing data and their use in personalised medicine or other innovation. We identified the need to consider legality, data protection of individuals, and the importance of trust. EU data law was very much in flux (pre-GDPR legislation); individuals might not have given 'broad' consent to the use of their hospital-collected medical data. Likewise, existing research repositories act as conservative guardians of individual data both legally and to maintain the trust of their own contributors. Individuals broadly supported use of their data for medical research but were less willing to do so if the benefits become privately-owned. The issue of data privacy and trust was a key early theme in Foresight Lab work that re-emerged throughout Human Brain Project activities.

Dual Use

Our research on 'dual use' concluded that this binary concept is inadequate to anticipate how neuroscience and neurotechnology can be used and misused (Mahfoud et al., 2018). Dual Use traditionally refers to research and technologies designed to benefit civilians but that can also be used for military purposes. It can also mean research and technologies that are used in 'good' and 'bad' ways. We found that in practice, these boundaries are blurred - research can be funded by both military and civil bodies, can be used by the military for civilian purposes, and what counts as misuse is not always clear cut. We argued that regulators and policy



makers must focus instead on harmful uses of neuroscience and neurotechnology in the following domains of application: political, security, intelligence, and military (PSIM) (Butorac, Lentzos, and Aicardi, 2021). To develop this expanded concept of dual use (Aicardi et al., 2021), we organised a series of workshops with scientists and engineers whose research we identified as more likely to raise dual-use issues of concern. Together, we co-developed science-fiction-like scenarios anticipating potential political, security, intelligence, and military uses of specific neuroscience and neurotechnologies - such as security concerns with open access supercomputing platforms. We found considerable awareness of, and concern about, these issues among the researchers themselves. These scenarios and discussions aided in the development of anticipatory capacities among HBP scientists and engineers, with the creation of a cross-project Dual Use Working Group (DUWG)¹⁵ (Ulinicane, Mahfoud and Salles, 2022).

Trust and AI

The centrality of ‘trust’ in the development of artificial intelligence (AI) and AI-enabled technologies is now widely documented. The Foresight Lab aimed to understand *if and how* (especially *the extent to which*) ‘trust’ becomes embedded in the practices of laboratories engaged with AI research and development (Aicardi et al., 2019). Our work emphasised strong interpersonal relationships based on trust between end-users of AI-enabled healthcare technologies (clinicians) and researchers (data scientists, modellers) as key to meaningful and successful technology uptake. Findings further revealed that strong trust relationships were typically founded on greater transparency both in the datasets used for developing algorithms and in the logic of algorithmic construction, but also in the meaningful and early integration of clinician’s real-world experience (tacit knowledge) of patients’ needs in development processes.

Debates around what meaningful research-practice collaboration *should* or *can be* are not new. Still, our work calling attention to their salience in technology development processes was a provocation. Our (implicit) contention that the poorly quantifiable, poorly measurable, non-technical aspects (e.g., trust relationships, tacit knowledge integration) play a substantive role in the development processes of highly technical knowledge systems (such as AI-enabled healthcare) has however recently gained increasing currency as more socially responsive frameworks of innovation are preferred. Our work takes this further to identify spaces of research-practice collaborations as areas where a renewed attention to trust-building can have profound implications by helping embed more socially responsive ‘technical’ aspects in innovation processes (Burton et al., 2021).

Community and Collaboration

Neuroscience is not a unified field of research. Instead, it comprises a great variety of approaches to understanding and investigating the brain, which translates into much fragmented ways of building brain models. Early in the HBP, we worked with some HBP modellers and neuroinformaticians to explore possibilities, issues, and practicalities of collaboration between brain modelling communities within and outside the HBP (Rose, Aicardi and Reinsborough, 2015c). It had important outcomes in terms of sociological research and neuroscientific collaborations. Its main, and unexpected, long-term impact on the HBP was to start the conversation with The Virtual Brain (TVB) that led to TVB joining and then becoming a key component of the HBP¹⁶.

¹⁵ Read more about the Dual Use Working Group: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/dual-use/>

¹⁶ Read more about The Virtual Brain (TVB): <https://www.thevirtualbrain.org/tvb/zwei>



The HBP is a uniquely large-scale project that brings together more than 500 scientists and engineers from a range of very diverse disciplines. This has presented important challenges. One is how to monitor and foster collaborations between HBP partners. In our research, we paid attention to the formal and informal ways that HBP scientists and engineers collaborate. A key finding was that making collaborations visible requires much work and that not all collaborations translated into the HBP infrastructure (Aicardi and Mahfoud, 2022). We anticipate that to retain the diversity of the HBP community, the EBRAINS infrastructure will need to acknowledge these ‘invisible’ collaborations and ensure an inclusive membership and governance, involving not only basic researchers but also representatives of those communities with an interest in the practical applications of this research.

Science Fiction

Throughout our work, we spent much time researching foresight methods, debating how we could realistically adapt them to the HBP given our time and budget, and eventually writing near-future fictional vignettes to kick off discussions at a stakeholders’ foresight seminar on future medicine that we co-organised in October 2014 and in various workshops thereafter. This first inroad into using science fiction in foresight work has led to various collaborations and projects with sci fi writers. We have organised many activities and events aimed at fostering researcher awareness, engaging with the public, and generating insights into social and ethical issues in other contexts than the HBP. It also led some in the Foresight Lab to experiment with the medium of science fiction to express aspects of their experience as social scientists integrated in the HBP that could not be captured by traditional academic writing.

Conclusion

Foresight is a valuable exercise, and we outline our achievements in the sections above: supporting community building within the HBP and with other cognate projects; methodological developments using sci-fi inspired scenarios; and contributions to establishing the dual use working group and institutionalising RRI (Aicardi et al., 2018). However, mechanisms are needed to ensure that it has traction on the priorities and direction of research. While we increased ‘awareness’ of key ethics and society issues among some HBP researchers, more work is needed to institutionalise RRI in lasting ways. This has been done with the dual use working group, for example. But this is especially difficult in large consortia of diverse research groups, each of which has its own priorities, and many of which are working on ‘basic science’ seemingly far removed from practical application. To be effective, foresight researchers need to be engaged ‘upstream’ and have accepted and valued roles with the governing bodies of projects like the HBP. There is still much to do in developing effective models that will build social responsibility and research for social benefits into the heart of such large research consortia as the HBP.

References

- Aicardi, Christine and Tara Mahfoud (2022). “Formal and Informal Infrastructures of Collaboration in the EU’s Human Brain Project.” *Science, Technology & Human Values*. Online First. <https://doi.org/10.1177/01622439221123835>
- Aicardi, Christine, Bitsch, Lise, Bang Bådum, Nicklas, Datta, Saheli, Evers, Kathinka, Farisco, Michele, Fothergill, Tyr, Giordano, James, Harris, Emma, Jørgensen, Marie Louise, Klüver, Lars, Mahfoud, Tara, Rainey, Stephen, Riisgaard, Karen, Rose, Nikolas, Salles, Arleen, Stahl, Bernd, & Ulinicane, Inga. (2021). Opinion on 'Responsible Dual Use' Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology. Zenodo. <https://doi.org/10.5281/zenodo.4588601>
- Aicardi, C., Datta Burton, S., Mahfoud, T., & Rose, N. (2019). Machine Learning and Big Data for NeuroDiagnostics: Opportunities and Challenges for Clinical Translation: A briefing report for the Human Brain Project. Deliverable of the Human Brain Project to the European Commission.

https://kclpure.kcl.ac.uk/portal/files/137218687/HBPForesightLab_2019_NeuroDiagnostics_BriefingReport_PUBLIC.pdf

Aicardi, C., Fothergill, B. T., Rainey, S., Stahl, B., & Harris, E. (2018). Accompanying technology development in the Human Brain Project: From foresight to ethics management. In Special Issue "New Directions in Catastrophic and Existential Risks." *Futures* 102 (September 2018): 114-124. <https://doi.org/10.1016/j.futures.2018.01.005>.

Aicardi, C., Reinsborough, M., & Rose, N. (2017). The integrated Ethics and Society Program of the Human Brain Project: Reflecting on an ongoing experience. In Special Issue "Neurotechnology and Society: Towards Responsible Innovation." *Journal of Responsible Innovation* 5 (1): 13-37.

<http://www.tandfonline.com/doi/full/10.1080/23299460.2017.1331101>

Burton, S., Mahfoud, T., Aicardi, C., Rose, N. (2021) Clinical translation of computational brain models: understanding the salience of trust in clinician–researcher relationships. *Interdisciplinary Science Reviews*. Special Issue "Artificial Intelligence and its Discontents" 46 (1-2): 138-157. <https://doi.org/10.1080/03080188.2020.1840223>

Butorac, I., Lentzos, F., Aicardi, C. (2021). 'Gray Matters: Exploring Technologists' Perceptions of Dual-Use Potentiality in Emerging Neurotechnology Applications', *Health Security* 19, no. 4, pp. 424-430.

<https://doi.org/10.1089/hs.2020.0147>

Mahfoud, Tara, Christine Aicardi, Saheli Datta, and Nikolas Rose. (2018) "The Limits of Dual Use." *Issues in Science and Technology* 34, no. 4. Available at: <http://issues.org/344/the-limitsofdual-use/>

Marris, Claire and Nikolas Rose (2012). "Let's get real on synthetic biology". *New Scientist*.
<https://www.newscientist.com/article/mg21428684-800-lets-get-real-on-synthetic-biology/>

Rose, N., Aicardi, C., & Reinsborough, M. (2015a). Foresight Report on Future Medicine. Deliverable of the Human Brain Project to the European Commission.

https://kclpure.kcl.ac.uk/portal/files/86508529/KCLForesightLab_2015_Future_Medicine.pdf

Rose, N., Aicardi, C., & Reinsborough, M. (2015b). Foresight Report on Future Neuroscience. Deliverable of the Human Brain Project to the European Commission.

https://kclpure.kcl.ac.uk/portal/files/86508305/KCLForesightLab_2015_Future_Neuroscience.pdf

Rose, N., Aicardi, C., & Reinsborough, M. (2015c). Future Neuroscience and the Human Brain Project. Building a Neuroscience Community: community modelling and data Repositories. Workshop report, Fondation Brocher, Hermance (Switzerland), 11 – 13 June 2015. <https://www.kcl.ac.uk/ghsm/assets/report-workshop-fondation-brocher-2015.pdf>

Rose, N., Aicardi, C., & Reinsborough, M. (2016). Foresight report on future computing and robotics: A Report from the HBP Foresight Lab. Deliverable of the Human Brain Project to the European Commission.

https://kclpure.kcl.ac.uk/portal/files/86508137/KCLForesightLab_2016_Future_computing_robots.pdf

Ulnicane, Inga, Tara Mahfoud and Arleen Salles. 2022. Experimentation, learning, and dialogue: an RRI-inspired approach to dual-use of concern. *Journal of Responsible Innovation*. <https://doi.org/10.1080/23299460.2022.2094071>

Neuroethics & Philosophy in the Human Brain Project

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Neuroethics

Neuroethics is an area of intellectual and social discourse that deals i.e., with our consciousness, identity, sense of self, and the values that we develop; it is an interface between the empirical brain sciences, philosophy of mind, moral philosophy, ethics and the social sciences. It is the study of the questions – e.g., theoretical, conceptual, or normative – that arise when scientific findings about the brain are carried into philosophical analyses, medical practice, legal interpretations, health and social policy, and can, by virtue of its interdisciplinary character, be seen as a sub-discipline of, notably, neuroscience, philosophy or bioethics, depending on which perspective one wishes to emphasize.

Many of the questions that modern neuroethics raises are not new, they were raised already during the French Enlightenment, notably by Diderot who stated in his *Eléments de Physiologie*: “*C'est qu'il est bien difficile de faire de la bonne métaphysique et de la bonne morale sans être anatomiste, naturaliste, physiologiste et médecin...*”¹⁷. Moreover, ethics committees throughout the world have long dealt with ethical problems arising from advances in neuroscience, though not necessarily under the “neuroethics” label.¹⁸ However, as an academic discipline labelled ‘neuroethics’, it is a very young discipline. The first “mapping conference” on neuroethics was held in 2002 (Marcus 2002), and references to neuroethics in the literature were made little more than a decade earlier.

Fundamental versus applied neuroethics

So far, researchers in neuroethics have focused importantly on applications, that is, on practical ethical questions that arise through neuroscientific advances such as those involved in neuroimaging techniques, cognitive enhancement, or neuropharmacology.¹⁹ This applied neuroethics is what Roskies (2002) has labelled “ethics of neuroscience” in distinction from “neuroscience of ethics” that is concerned with whether and how neuroscientific knowledge can offer explanations of the nature and development of moral thought and judgment. This oft-quoted distinction is indeed useful, but it is not exhaustive in the sense that the field of neuroethics does not only comprise neuroscience and ethics but also philosophy, notably philosophy of science, and a wide range of issues that the distinction fails to cover.

If, in contrast, “applied neuroethics” is distinguished from “fundamental neuroethics”, the distinction may include further areas than ethics and neuroscience and become more far-reaching if not exhaustive.

Three core features, related to topic and to methodology, distinguish fundamental neuroethics (a concept introduced by Evers 2009): it pursues *foundational* analyses within a *multidisciplinary* research domain using an *interdisciplinary* methodology (Evers 2023). 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 – in line with the above quote from Diderot – it involves

¹⁷ This work is a collection of writings by Diderot starting in 1774 but the book was not published until 1875: *Œuvres complètes de Diderot*, édition établie par J. Assézat et M. Tourneux, t. IX, Paris, Garnier, 1875. The above quote is from II.djvu/332, page 136. The quote is well in line with “fundamental neuroethics” presented in this essay.

¹⁸ Cf., e.g., Opinions by the *Comité Consultatif National d’Éthique*, France in the 1980s.

¹⁹ A review of numerous such issues is provided in Illes (2006).

elements from different disciplines, including 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 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. Yet since all form 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).

Fundamental neuroethics as a key component of European research and innovation in neuroscience

The European Commission has significantly supported science in the European Research Area to deepen our understanding and improve our knowledge of the brain. Fundamental neuroethics has played an essential role in that process, embedding it as a critical component from the very start, notably in the Horizon 2020 Future and Emergent Technologies (FET) Flagship "The Human Brain Project (HBP)".

Fundamental to the HBP approach is to investigate the brain on different spatial and temporal scales (i.e. from the molecular to the large networks underlying higher cognitive processes, and from milliseconds to years). To achieve this goal, the HBP relies on the collaboration of scientists from diverse disciplines, including neuroscience, social science, philosophy and computer science, to take advantage of the loop of experimental data, modelling theories and simulations. The idea is that empirical results are used to develop theories, which then foster modelling and simulations, which result in predictions that are in turn verified by empirical results and further clarified by conceptual/theoretical analyses.

From the earliest planning stages and the beginning of the project, HBP core research has comprised social science and humanities, including philosophy and neuroethics, joined in what was called "Ethics & Society Subproject" (one of 11 research subprojects in the HBP).²⁰ Other major Brain Initiatives (in e.g. in the US, China, Japan, Canada and Australia) have ethics monitoring, ethics regulations and ethical advisory boards but they comprise no dedicated research in those areas, which makes the HBP unique in this regard (Evers 2017).

The philosophy and neuroethics research²¹ has been largely devoted to fundamental neuroethics. This research has *inter alia* focused on the following topics²²:

- a) Simulation (e.g., Dudai & Evers 2014, Farisco et al. 2018)
- b) Neuronal epigenesis and cultural imprinting on brain architecture (e.g., Evers 2016a, 2020, Evers & Changeux 2016)

²⁰ In financial terms: social science and humanities research has received ≈5% of HBP's total budget. A quarter of that was dedicated to philosophy and neuroethics, which accordingly received ≈1,25% of the HBP's total budget.

²¹ The Neuroethics & neurophilosophy group at the Centre for Research Ethics & Bioethics (CRB), Uppsala University, is in charge of this research in the HBP and related teaching. More details about the Neuroethics & neurophilosophy group at Uppsala University can be found at: <https://www.crb.uu.se/research/neuroethics/>

²² Other topics that have been addressed are: Responsible Research and Innovation (RRI) (e.g., Salles et al 2018, 2019), Dual Use (e.g., Giordano & Evers 2018) and Data Protection and Privacy (e.g., Farisco & Evers 2016, Salles 2016). The research has been complemented by teaching and seminars, e.g. a series of higher seminars by M. Guerrero on "Social praxeology and neuronal epigenesis" (2018); "Sound, listening practices and music" (2018); "Towards and ethics of Neurorobotics" (2019); "The socialized body" (2020).

- c) Consciousness, brain disorders and neurotechnological mind-reading (e.g., Evers & Sigman 2013, Farisco et al. 2015, Pennartz et al. 2019)
- d) Digital Twins and Virtual Brains (e.g., Evers & Salles 2021)
- e) Artificial intelligence (e.g., Salles et al. 2020).

Importantly, this focus on fundamental neuroethics research does not imply that applied neuroethics research is ignored: to the contrary, it is considered to be an important task for fundamental neuroethics to provide the theoretical foundations that can be clearly and adequately communicated and thereby enable informed analyses of applied issues and help ensure beneficial applications. For example, the philosophical analyses of consciousness are directly connected to clinical applications to benefit, notably, patients with disorders of consciousness (Farisco & Evers 2017), as well as people who suffer from drug addiction (Farisco et al. 2018a). The analyses of cultural imprinting on brain architecture have, e.g., been used in connection to understanding the effects of poverty on brain development (Lipina & Evers 2017). Fundamental neuroethics has also been a key component in strengthening responsible research and innovation practices.

Thus, in fundamental neuroethics, theory and practice complement each other. An advanced and refined theoretical framework combining clearly described scientific data and hypotheses with well-defined terminology helps to ensure the best possible use of the results. Vice versa, a successful application may provide the theoretical framework with crucial substance and justification.

The mutual relevance of theory and practice, as fundamental research and applications feed into each other, has come to expression not least in the Opinions that HBP's Ethics & Society Subproject published on a variety of topics: Opinion and Action Plan on 'Data Protection & Privacy' (2016), Opinion on 'Responsible Dual Use' Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology (2018), and Opinion on Trust and Transparency in Artificial Intelligence (2021). These Opinions all combine conceptual analyses of key concepts with social science and ethics studies, forming a solid basis for recommendations on how to approach and manage the topics in question. They are also combined with concrete action plans to guide their implementation²³.

References

- Dudai Y, Evers K, To Simulate or not to Simulate: What are the questions?, *Neuron*, 2014;84(2):254-261.
- Evers K, Neuroéthique. Quand la matière s'éveille. Éditions Odile Jacob, Paris 2009. (Spanish transl. Neuroética. Cuando la materia se despierta, Katz Editores, Buenos Aires 2010.)
- Evers K, Sigman M, Possibilities and limits of mind-reading: A neurophilosophical perspective, *Consciousness and Cognition*, 2013;22:887–897.
- Evers, K, Can we be epigenetically proactive? In T. Metzinger & J. M. Windt (2016a) (Eds). *Open Mind: Philosophy and the mind sciences in the 21st century*, MIT Press, Cambridge, pp. 497-518.
- Evers K, Changeux J-P, Proactive epigenesis and ethical innovation. A neuronal hypothesis for the genesis of ethical rules, *EMBO Reports*, 2016; 17 (10): 1361-1364.
- Evers K, The contribution of neuroethics to international brain research initiatives, *Nature Reviews Neuroscience*, 2017; 18:1-2.
- Evers K, Fundamental Neuroethics, in Farisco M (ed.), *Neuroethics and Cultural Diversity*, ISTE-Wiley, London 2023, forthcoming.

²³ The Opinions can be read and downloaded from the HBP's website: <https://www.humanbrainproject.eu/en/social-ethical-reflective/publications/>

Evers K, Salles A (2021) Epistemic Challenges of Digital Twins & Virtual Brains: Perspectives from Fundamental Neuroethics. SCIO Journal of Philosophy. 21; 27-53. DOI: https://doi.org/10.46583/scio_2021.21.846

Farisco M, Evers K, The ethical relevance of the unconscious, *Philos Ethics Humanit Med.* 2017 Dec 29; 12(1):11. doi: 10.1186/s13010-017-0053-9.

Farisco M, Laureys S, Evers K, Externalization of Consciousness. Scientific Possibilities and Clinical Implications, in: Geyer M, Ellenbroek B, Marsden C (eds), *Current Topics in Behavioural Neurosciences*, 2015; 19: 205-222, doi: 10.1007/7854_2014_338.

Farisco M, Hellgren Kotaleski J, Evers K, Large-scale brain simulation and disorders of consciousness: Mapping technical and conceptual issues. *Frontiers in Psychology*, 2018; 9: 585 doi: 10.3389/fpsyg.2018.00585.

Farisco M, Evers K, Changeux JP, Drug addiction: from neuroscience to ethics. *Frontiers in Psychiatry*, 2018a; 9: 595 doi: 10.3389/fpsyt.2018.00595.

Lipina S, Evers K, Neuroscience of Childhood Poverty: Evidence of Impacts and Mechanisms as Vehicles of Dialog With Ethics, *Frontiers in Psychology*, 2017; 8: 61.

Marcus, S. J. (ed.): 2002, *Neuroethics: Mapping the Field*, Conference Proceedings, May13-14, 2002, San Francisco, California, The Dana Press, New York.

Roskies, A.: 2002, 'Neuroethics for the new millenium', *Neuron*, 2002; 35: 21-23.

Salles A, Bjaalie J, Evers K, Farisco M, Fothergill T, Guerrero M, Maslen H, Muller J, Prescott T, Stahl B C, Walter H, Zilles K, Amunts K, The Human Brain Project: Responsible Brain Research for the Benefit of Society. *Neuron*, 2019; 101:3; DOI <https://doi.org/10.1016/j.neuron.2019.01.005>.

The Human Brain Project (HBP), Neuroethics and the International Brain Initiative (IBI)

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Introduction

Advances in neuroscientific research and the availability of big data offer significant opportunities for enhancing our understanding of the brain and for the development of diverse neurotechnologies. As discussed in several essays in this collection, awareness of the potential ethical and social issues raised prompted the HBP's Ethics and Society team to develop a number of mechanisms and structures within the responsible research and innovation (RRI) framework promoted by the European Commission (Salles et al., 2019; Salles, Evers and Farisco, 2019; Stahl et al., 2021). The implementation of this framework has included the development and use of different neuroethical methodologies and approaches (see essay by Evers in this volume). The HBP's work on neuroethics has contributed to international discussions on how to carry out reflection on responsible neuroscience and neuroinnovations in general. Importantly, since 2016, the HBP has collaborated with existing large scale brain research initiatives in identifying and addressing potential impacts of brain research and applications. This collaboration is the focus of this short essay.

The Global Neuroethics Working Group was formed in 2016 to address some of the ethical and social challenges facing national and supranational brain initiatives²⁴. A year later, in December 2017, a group of representatives from the major brain research projects announced a Declaration of Intent to establish the International Brain Initiative. What is known as the Declaration of Canberra²⁵ stated that international collaboration and knowledge sharing are key for scientific research to benefit humanity. Importantly, it specifically acknowledged the need for attention to neuroethical and social issues and for international collaboration in identifying and addressing them. At that time, the Global Neuroethics Working Group became the IBI Global Neuroethics Workgroup (IBIWG)²⁶.

From its creation, the main aim of the IBI Global Neuroethics Workgroup has been to advance responsible, ethical, and culturally aware brain research and technology. To do so, it has acted as a convener, ideas incubator, and community builder, advancing responsible, ethical, and culturally aware neuroscientific practices by bringing together the insights gained from diverse neuroethics research and activities in the respective brain initiatives. The group was initially constituted by representatives from the HBP, US BRAIN, Japan's Brain/Minds, and the Korean Brain Initiative in addition to consultants from the Canadian Brain Research Strategy, the Australian Brain Initiative, and the China Brain Project.

The IBI Global Neuroethics Workgroup group organised and coordinated multiple interdisciplinary and international meetings. Moreover, emphasizing the significance of attention to cultural awareness and engagement, it also focused on developing and completing rapid deliverables, be it peer reviewed publications or reports on specific topics (Das et al., 2022; Global Neuroethics, 2018). Furthermore, mindful of the multi and interdisciplinary character of neuroethics, the group systematically consulted with experts from different disciplines, from STS researchers, neuroscientists, and philosophers, to neuroengineers and

²⁴ Read more about the Global Neuroethics Working Group here: <https://globalneuroeticssummit.com/>

²⁵ Find the declaration here:

<https://www.internationalbraininitiative.org/sites/default/files/files/IBI%20Declaration%20of%20Intent%202017.pdf>

²⁶Read about the Neuroethics Working Group: <https://www.internationalbraininitiative.org/neuroethics-working-group>



engagement practitioners, to achieve a more complete understanding of the issues and to promote a more comprehensive reflection on potential solutions. All deliverables have been shaped by conversations and feedback from diverse communities of experts from the natural and social sciences and the humanities.

IBI Global Neuroethics Workgroup: Some Topics and Activities

In the inaugural 2017 Global Neuroethics Summit, leading scientists, bio and neuro-ethicists, and humanists discussed and developed a list of neuroethics questions that should be addressed by scientists in each brain project. The questions revolved around issues such as data collection and protection, the moral significance of engineered neural circuitry, brain interventions and autonomy, dual use, and misuse in neuroscience, among others. While they did not necessarily address novel concerns, they were formulated and designed to be culturally sensitive and adaptable to the values, ethical frameworks, and contextual considerations of each region (Global Neuroethics Delegates et al., 2018). The questions played an important role in the following the 2018 Global Neuroethics Summit (GNS) where diverse representatives from each of the brain projects discussed and assessed their efforts to integrate neuroethics into their projects with a focus on the issues addressed by the questions.

A theme that emerged as deserving of special attention from these two meetings was the importance of meaningful neuroethics engagement with diverse publics. Thus, during 2019 the IBIWG and the HBP co-organized a workshop on this topic, and later devoted the annual meeting (Global Neuroethics Summit, 2019) to addressing existing and novel engagement strategies and creating good engagement practices for public engagement in a variety of cultural and geographic settings.

In 2020, the IBIWG set about strategising toward neuroethics integration with neuroscience specially 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 integration in the neuroscience community²⁷.

As is to be expected, within the different international brain initiatives the status and operationalisation of neuroethics is uneven. In some of these projects, neuroethics is seen fundamentally as ethics compliance. In others, 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. Still, even in the best cases challenges to integration remain.

From December 2020 to December 2021, the IBI Global Neuroethics Workgroup undertook several activities to map and assess neuroethics and neuroscience integration efforts, reflect upon the need for such integration, and identify significant challenges. This entailed addressing questions such as: how is neuroethics understood in the different brain projects? What is the role of neuroethics and why is the field important? What counts as integration? How should integration be implemented? Addressing these questions resulted in the identification of conceptual, evaluative, and structural challenges to integration of neuroethics and neuroscience. How to better address those challenges continues to be discussed at present in different (academic, regulatory, policy making) settings (see essay by Rommelfanger in this volume).

Looking ahead

Engaging and working with the different international brain initiatives has enabled a rich neuroethics discussion of some of the issues more directly relevant to these projects. While unveiling and addressing

²⁷ <https://globalneuroethicssummit.com/>

ethical and social issues is always a work in progress, this international team effort has led to a clearer understanding of common challenges in ensuring the development of responsible neuroscience research and innovation and more awareness of the need to recognize cultural and contextual considerations. Importantly, it has reaffirmed the need for continuous collaborative work to identify and address emerging challenges and co-create ways to implement actionable solutions.

Note: This text was shaped by the numerous interactions of the author with members of the original Global Neuroethics Workgroup of the International Brain Initiative. Some of the ideas have been further developed in joint scientific publications with the group and through collaborative work in the HBP.

References

- Das, J., Forlini, C., Porcello, D., Rommelfanger, K., Salles, A., and Delegates, G.N.S. (2022). Neuroscience is Ready for Neuroethics Engagement. In SSRN.
- Global Neuroethics Summit, D., Rommelfanger, K.S., Jeong, S.J., Ema, A., Fukushi, T., Kasai, K., Ramos, K.M., Salles, A., and Singh, I. (2018). Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives. *Neuron* 100, 19-36.
- Salles, A., Bjaalie, J.G., Evers, K., Farisco, M., Fothergill, B.T., Guerrero, M., Maslen, H., Muller, J., Prescott, T., Stahl, B.C., et al. (2019). The Human Brain Project: Responsible Brain Research for the Benefit of Society. *Neuron* 101, 380-384.
- Salles, A., Evers, K. & Farisco, M. (2019). Neuroethics and Philosophy in Responsible Research and Innovation: The Case of the Human Brain Project. *Neuroethics* 12, 201–211.
- Stahl, B.C., Akintoye, S., Bitsch, L., Bringedal, B., Eke, D., Farisco, M., Grasenick, K., Guerrero, M., Knight, W., Leach, T., et al. (2021). From Responsible Research and Innovation to responsibility by design. *Journal of Responsible Innovation* 8, 175-198.



From Stakeholder Engagement to Community Building

Lars Klüver (Danish Board of Technology Foundation)

Introduction

On a time-limited and project scale there are many effective and proven methods for multi-actor and quadruple-helix engagement. Methods such as Living Labs or Scenario Workshops, and a wide diversity of organizational structures from inclusion of stakeholders into consortia, over Stakeholder Boards, and to open and continuous dialogues in Stakeholder Forums, have been used to ensure that the voices of a variety of experts and stakeholders are listened to along the science, innovation, and implementation activities in projects. Likewise, citizen engagement in science and innovation – or Citizen Science, as it is increasingly termed – on a project scale is well-established for all phases of the science-to-innovation-to-society paths.

We know how to engage stakeholders, multi-actors, and citizens for visioning, cocreation processes, crowd science, policy development and definition of research and innovation challenges. The question appeared, though, about how this knowledge can be transferred to an effective multi-actor engagement connected to an enduring, sustainable, and open research infrastructure: How can EBRAINS become not only an infrastructure of computers and software, but also an enduring infrastructure of people that collaboratively want to turn science into benefits for society and its citizens? Or more operationally phrased - can an inclusive approach to Community Building deliver on the need for quadruple-helix collaboration? Such an “Inclusive Community Building” approach was explored and implemented in the last three years of the Human Brain Project with a view to continuation in EBRAINS.

Community building paradigms

Community building can, roughly speaking, aim at three different kinds of communities²⁸. In the most basic form of community the members are loosely coupled Users, meaning that nearly all community activity is decided and managed centrally, and the members’ main interest is to individually make use of a certain well-defined technical or service offer. A more advanced community sees the member as a sort of B2B customer, thus having some dialogue with and delivers communication channels between the members, often in the form of a forum’s setup, so that the members can help each other. In the ‘networked’ and most advanced communities the members are collaborators that bottom-up take co-responsibility for the community, and for development and use of services. Importantly, what binds this form of community together is that the members share certain goals, need to collaborate to achieve them, and the community facilitates that.

These three community types can each constitute a wished final state of community. But they also characterise steps that most communities need to take to reach the highest community maturity level of a networked community.

The vision of a highly mature EBRAINS Community

For several reasons the EBRAINS Community has been designed to over time accomplish the highest maturity level of a networked community. **Firstly**, EBRAINS is a goal-oriented infrastructure with the stated mission of supporting science and innovation towards understanding the brain and of bringing benefits to society and the citizens. This embraces very many kinds of aims, such as developing neuro-inspired computing, providing new diagnostic tools for clinicians, innovating brain technologies, and supporting tool and data sharing

²⁸ For insight into community maturity levels the Community Roundtable provides access to many valuable resources <https://communityroundtable.com/>

among scientists. To reach these goals, collaborations must be established, and the community should be designed to facilitate that.

Secondly, EBRAINS is not one piece of SaaS service – it is a heterogeneous collection of tools, workflow designs, data sharing and access services, and much more. It is a complexity of flexible and combinable SaaS services. Therefore, the community must be able to connect members with overlapping needs and interests, which has led to the structuring of subcommunities. The EBRAINS Community platform has been developed to support at least four forms of subcommunities – Service-based, Thematic, National, and Innovation subcommunities – each giving members the option to join those of their main interests and needs.

Thirdly, achieving the ambitious aims of understanding the brain and develop benefits to society can only be realised by including a wide array of stakeholders and multi-actors in collaborations. Research and innovation will have to have a whole-of-system and whole-of-value-chain approach being inclusive and drawing on very many competencies in society. It will have to be anticipatory about the end-use and societal implementation of its results. In other words, instead of involving multi-actors ad hoc, they must be seen as an integrated part of the community and the development of collaborations.

Fourthly, the future of brain science and innovation is “Big Science” and EBRAINS will technically become able to facilitate that. The community also needs to. Over time it will have to be able to connect thousands of people from science, the health sector, industries, civil society organisations, authorities, and funders. Big Science is scientific, but it is also economy, international collaboration, policy, and a fighting field about the direction of funds and societal attention. Facilitating parts of such discussions and processes is something that a core Big Science infrastructure will have to be ready to do.

There are certainly arguments pro and con such considerations about a widely inclusive EBRAINS Community and, for sure, the idea of this community will develop over time. The community will have to develop vis-a-vis and support the evolution of EBRAINS. Nobody can tell where this development will end, and how well it can succeed with facilitating deep collaboration between multi-actors. For the final three years of the HBP, it was the goal to initiate the development towards a highly mature community, with the hope and intention that it can help reaching important societal goals for health and other societal goods.



Public Engagement on Data governance and Brain Research

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Public engagement in the Human Brain project

The Danish Board of Technology has developed public engagement in the Human Brain Project (HBP) since the beginning of the project in 2013. Within the processes we developed, the focus was always on engaging citizens as well as professionals in deliberation on ethical and social issues of immediate, as well as more long-term societal interest and impact. Our aim being to learn more about the needs, values, concerns, and recommendations of the publics we involved. This public engagement process, we present here, aimed at providing input useful for developing an EU research infrastructure, EBRAINS so that it would be *societally responsible*. The process provided insights into the public opinion on data governance and brain research. It also empowered citizens to become involved in science development and thereby becoming aware of their rights in relation to their own health data. Finally, as the recommendations we present below will show, European citizens have thoughtful views about brain research and how a research infrastructure should be managed and by whom.

Developing the engagement activity

In 2020, The Danish Board of Technology started developing the final round of citizen engagement processes in the Human Brain Project (HBP). Several engagement actions had been undertaken previously on specific topics, such as data protection, dual use, and AI. Going into the final stages of the HBP, our public engagement efforts were inspired by interactions with the neuroethics working group of the International Brain Initiative (IBI). In 2019, the IBI neuroethics working group initiated what they called a “year of engagement”, to explore the potential of public engagement for neuroethics and for the integration of neuroethics and neuroscience. Inspired by interactions with the neuroethics working group, we set out to develop a method for engagement that could scale globally. Likewise, the topic of the engagement process should be recognised as an important and necessary one to explore by neuroethicists, brain researchers and others working on the development of the EBRAINS AISBL and research infrastructure and on global collaboration on brain research.

A methodology of engagement was developed that combined digitally supported, small-scale face-to-face meetings, with face-to face workshops. Experience with the digitally supported meetings had been built up through the HBP, and the approach and software was developed for use in multiple languages²⁹. For the workshops, we developed a concept of mixing lay citizen participants with expert participants for a day-long deliberation³⁰. Experience from previous engagement activities in the HBP and elsewhere, had inspired us to think that closer interaction between the lay citizens and experts was needed for better up-take of the outcome of the deliberations.

In a similar fashion, the topic of the engagement process was developed together with researchers and others from within the HBP. The motivation was to align on the goal of the engagement process with people in the project to increase chances of uptake of the results. The topic chosen was *disease signatures*. Disease

²⁹ We call this method GlobalSay. It follows the method of Citizen Hearings, but transports that into an online format for people to meet in their own homes.

³⁰ We call this approach Mixing of Minds (MoM).

signatures for brain disorders have been a focus of the HBP from its outset, and it is an emergent area of research upon which many expectations are placed.

Developing the digitally mediated meeting format required the development of easy-to-understand information on the ethical issues, that lay citizens could use to inform themselves on the different challenges, concerns, and opportunities, before sitting down to deliberate prepared questions with a group of invited guests. Methodologically, the small-scale meetings are characterised by self-selection and self-organisation by citizens and the digital platform takes over the role of meeting facilitator. To facilitate an easy uptake of information for citizens with different starting points, we used short graphic videos as a quick, easy, and inclusive way to inform citizens of some of the different dilemmas related to disease signatures (e.g., some citizens are less used to reading texts, and so the video format is more friendly to someone not so comfortable with reading text). Each video focused on one ethical issue. In total four issues were selected for a video: introduction to disease signatures, sharing of personal health data, collaborations, and use of disease signatures. Challenges to creating such videos included resolving issues such as what questions to ask and how to phrase them to avoid as influencing the attitude of participants and finding ways of simplifying complex issues without losing important details relevant to understanding and issue.

The next step was the development of the format of the workshops. Taking the design principle of supporting an equal, and deliberative dialogue with an emphasis on listening and learning as a starting point, the workshop set-up was divided in two main parts. A morning session for the citizens alone to get the right information and be able to formulate their views without being influenced by the experts. A second session involved both citizens and experts, where they collaborated on the further development of the work from the first session. To best inform the citizens, the videos from the small-scale meetings were re-used for the workshop. The videos were planned to inform citizens on the complex topic of disease signatures. They were short, in their native languages and cost-efficient. In short, the two processes were characterised by:

Digitally supported meetings:

- Distributed
- Digitally supported
- Self-organised
- Citizens only – groups of friends, relatives, colleagues, or others

One-day workshops with citizens and experts:

- Fixed location
- Full day workshop
- Citizens and experts together
- Professionally moderated

Execution and results of the process

The engagement process took place in six different European countries; Denmark, Germany, Hungary, Italy, Spain, and England, through the autumn of 2021 until the summer of 2022. All content was translated into the native language of each of the six countries. In total, more than 450 European citizens and 25 experts across six European countries through were engaged in the process. The output was analysed both per country and combined across countries.

Lessons learned on values and needs of EU citizens for an EBRAINS infrastructure that is societally responsible

The present engagement process yielded 5 recommendations³¹:

- **Establish a multidisciplinary and independent European board** to oversee and control the collection, access and sharing of data. A board must also ensure overall compliance with ethical guidelines.
- **Communicate outcomes from brain research to the European public in a broad, transparent, and non-scientific way.** The results are public goods, and better efforts must be made to ensure that citizens are educated about the outcome of health research and how to engage with it.
- **Increase research focus on prevention and understanding rather than primarily medical treatment.** This entails focus on the societal impacts on brain health as well as the interplay between brain health and socio-cultural factors. Therefore, brain research should prioritise engaging with the public, including patients and citizens.
- **Change funding priorities for brain research to improve distribution.** It should be a priority to broaden the distribution of funds and to also ensure funding for non-profit research. This includes better ethical guidelines for funding as well as maximising the funding to include overlooked brain diseases.
- **Implement a citizen-centred approach to data collection, privacy, and security.** This implies designing consent forms that are understandable for the general European citizen and to initiate public education about how individual health data is stored, can be accessed, shared, and utilised.

From the recommendations, citizen values include security, control, ethical oversight, communication, dialogue and giving back to society. They also prioritise prevention, and research into overlooked brain diseases and more knowledge on the interplay between brain health and socio-cultural factors. Finally, the value more information about how their data is used in combination with better designs of consent forms.

Looking towards EBRAINS (or any other data-based research infrastructure for disease research), the recommendations could be built into the infrastructure in several ways. The EU citizens concretely recommend a multidisciplinary and independent European board. It is possible this could be a solution. Other options/combinations could also be to find inspiration in the data governance framework developed within the HBP³².

EBRAINS is designed as a network, bringing together national actors across nation states of the EU. Actors within these networks could be called on to organise dialogue and communication with local communities. To give back insights coming from EBRAINS research, but also to regularly collect ideas and needs to inspire research priorities and topics in the network. Such a network structure could also be utilised for education, and for new research project that would co-create and test new consent forms and approaches to data collection, access, and use. Going forward, EBRAINS and other similar research infrastructures societal license to operate should depend on the degree to which they engage and include citizens and other societal actors. Science and research are social, and often-time publicly funded activities, with the ambition to improve all our lives. All could therefore be potentially affected by ongoing and future brain research. Therefore, citizens and others, have a right to be heard. Additionally, engagement, dialogue and co-creation can open to new ideas, knowledge, and perspectives, that can itself spark innovation and discovery in science.

³¹ The recommendations and the analysis on which they are based can be found here:
<https://tekno.dk/app/uploads/2023/02/HBP-Citizen-views-on-data-sharing.pdf>

³² Read more about the framework: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/data-governance/>



Responsible Data Governance in HBP & EBRAINS

Damian Eke (De Montfort University)

Introduction

Data Governance is/was an integral part of the Human Brain project and EBRAINS. Data Governance for us is the overall management of the availability, usability, integrity, and security of data used in an organisation. A sound data governance programme ensures that data are consistent, compliant, and trustworthy. The overall data governance framework is shaped for relevant EU laws and ethical principles. Therefore, HBP/EBRAINS data governance framework aligns with EU data governance regulations (e.g EU General Data Protection Regulation GDPR and the provisions of the EU Strategy for data, including policies and regulations within the EU Health Data Space). In the case of animal data, the EU Directive 2010/63/EU on the Protection of Animals used for Scientific Purposes shapes EBRAINS governance mechanisms. Including the interests and expectations of the society is critical to the effectiveness of data governance models. To address this, HBP/EBRAINS adopt the PPT (People, Processes, Technologies) data governance model/framework.

The **People** include all identified stakeholders within all the data processing pipelines in EBRAINS, who are responsible for creating, applying, and maintaining data governance procedures. It also includes the identification of data subjects whose rights must always be upheld. Most importantly for HBP/EBRAINS, the stakeholders are established groups or committees to consider the interests of the data subjects include: the Data Governance Working Group, the Data Protection Officers, the Access Review Committees, and the Curation Access Review Committee. There are also **Processes** - referring to the diverse technical, legal, and ethical policies, procedures and practical processes set up to ensure responsible data governance. Finally, there is also **Technology** which includes all technologies developed and applied in EBRAINS workflows to ensure usability, FAIR and compliance to relevant laws and ethical principles.

The major achievement of data governance activities in HBP/EBRAINS is a *RESPONSIBLE process* that integrates ethics, laws, and societal values into data processing activities. Data Governance in EBRAINS can be described as 'Responsibility-by-design'. At each stage of the data processing workflow, elements of ethics and the law are integrated into the design. These were achieved via established and actionable policies, processes and procedures in addition to technologies such as: EBRAINS Human Data Gateway (HDG), metadata standard OpenMINDS, pseudonymisation and Encryption.

In doing responsible data governance we have learnt that data Governance without consideration of the interests of the society is non-efficient and non-compliant. Another lesson learnt is that the changing landscape of technology has immense impact on effective and compliant data governance. Also, diverse interpretations of the law present challenges to effective DG and many ethical issues are currently missing from the data governance discourse such as bias and diversity of research data.

Therefore, the hope is to expand DG in EBRAINS to address issues such as of lack of diversity of datasets, animal welfare differences and quality of data; provide harmonised interpretation of the GDPR for specific use cases in neuroscience research and innovation and include empirical insights from citizens into the established data governance model.

However, current challenges include additional legal provisions to consider in the EU Health Data Space and continued interactions with different legal provisions.

Beyond and Beyond Beyond Compliance in the Human Brain Project

William Knight (De Montfort University)

Introduction

Even amongst international research projects, the EU FET Flagships were ambitiously proportioned. The HBP spanned (at various points in its decade-long lifetime) 145+ different universities, hospitals, and research institutions across 45+ countries. In the final phase of the project, running from 2021-2023, there were over 100 different “tasks” ranging from theoretical neuroscience through to very technical platform development.

The ethical management of this constellation of research activity was a complex and multi-faceted challenge. The HBP was developed from its earliest stages to be a project with a strong ethics component and with a commitment to Responsible Research and Innovation. Not only must the HBP ensure that the projects under its umbrella are acting within the bounds of the law, but also, they have responsibilities to demonstrate that compliance to both the funder and the wider public. So - considering the significant challenge of scale: how do you build a meaningful ethics compliance structure in such a project?

We needed a process which could account for a wide variety of potential ethical challenges: research involving living human subjects, non-human primate subjects, the handling of personal data and, eventually, the potential for interaction with artificial intelligence.

One tactic might have been to fall back on simplifying the management of ethical challenges down to a simple “tick-box” exercise: does the project have approval from their local institution, yes/no? If the principal investigator has a valid ethical approval already, then that should serve as an indicator that the research activity has met its requirements to the satisfaction of that local committee that issued the approval letter. This approach is low-investment and low-effort, but on the surface, it might appear to meet the needs of ensuring that HBP research has appropriate approvals.

This minimalist approach, however, would separate the compliance responsibilities of researchers from more meaningful ethical inquiry. The message sent to researchers would be “these requirements are merely an administrative exercise”, and the conclusion which they might draw could be “they are unimportant”. So, we built a process which goes beyond simply checking off boxes.

A dialogical approach to compliance

The resulting ethics compliance processes were developed and deployed over the course of several years, and in each phase of the project we sought to iterate upon what we had learned over the previous phase. We aimed to build a compliance process which accounted for the massive scale of the HBP, whilst allowing for the process to involve dialogue, discussion, and negotiation. Through this process we were able to not only ensure that the HBP met expectations with regards to ethics compliance, but that we capitalised upon the opportunity that having a robust ethics compliance structure can be for a project.

The development of this compliance process was not without its own challenges. Early attempts to manage the ethics of the HBP were met with unsatisfactory reviews, they did not wholly capture the research activity of the project in such a way as to demonstrate that the project was compliant, and so we iterated on our approach. We introduced a systematic collection of the details of every task, and introduced methods through which a greater level of cooperation and communication could be engendered between the science-based work packages of the project and the ethics support team. Vital to this approach was an acknowledgement of the limitation of research ethics as a practice: ‘the key problem of current research ethics is that to some degree it achieves the opposite of what ethics should do. Instead of opening,

questioning, and debating ethical questions, it closes them down and removes them from critical scrutiny. Furthermore, it removes reflection upon ethical issues from the research process and makes shared forms of responsibility impossible' (Stahl et al 2019:5). Compliance should only be part of the overall approach to the ethical management of a project, and so for the HBP we implemented an approach built upon the idea of ethics dialogues (Stahl et al, 2019): an inclusive and discursive approach which involves the practical engagement with all the stakeholders in the research process. Examples of this approach in action are the ethics rapporteurs: scientists based in the established scientific work packages who took on an additional responsibility to act as a liaison between those work packages and ethics support. Another example is the annual "trilateral" meetings where work package managers, ethics rapporteurs and other scientists met with the ethics support team to discuss the potential ethical issues in the scientific activity of the work package. Both the ethics rapporteurs and the trilateral meetings were important contributors to the ethics compliance process, and the success of that process was only achieved because of that dialogue.

Even in the later stages of the project, this approach still required iteration and improvement. It is expected that over the course of a decade there will be highs and lows in any endeavour. Across the decade we faced challenges both familiar and novel, some remain and some we were able to overcome, but in the penultimate European Commission review in May 2022 the HBP was able to, for the first time, obtain the highest "excellent" rating in their ethics review.

Now, as the project draws to a close, we naturally consider what we can learn from this unique experience. The HBP ethics compliance process has been successfully implemented in the EBRAINS infrastructure³³, but for that success to continue we must look back across the decade of compliance management in the HBP and draw out those insights which can feed into the infrastructure's compliance process. One key insight is to take compliance seriously, just as the HBP did, and invest resources into it - because it is not just an administrative exercise, but it is also an opportunity.

Compliance can be an Opportunity

When a researcher is considering the ethical implications of their work, their first consideration will likely be "what do I *have* to do?" and so their first port of call when considering the ethical implications may well be the compliance officer/manager in their institution.

The compliance manager is usually a well-known person amongst the research community at an institution as speaking with them is an important step in setting up a research project. They are likely to be viewed as more accessible than those individuals at an institution with more specific expertise (such as experts on more specific ethical challenges embedded in research projects or working as independent academics). The compliance managers' utility is well understood – a researcher may not have a firm grasp on what their responsibilities are to stakeholder engagement or data governance, but they are very likely to at least understand that there are rules and regulations they will be expected to follow. So – the compliance manager may well be the researchers' first step in the consideration of their ethical responsibilities. This interaction, then, is an opportunity. It is an opportunity for the compliance manager to inquire, engage and educate:

Inquire – The compliance officer can ask the researcher about their preparedness to manage ethical challenges in their work, they can work with the researcher to discover what ethical issues are raised by their work and what measures they can put in place to account for them.

³³ Read more about EBRAINS: <https://ebrains.eu/>

Engage – The compliance officer can challenge the researchers' preconceptions, raise issues in their work that the researcher might not have considered and push the researcher to consider new approaches or ways of thinking.

Educate – The compliance officer can point the researchers towards ideas and concepts that might help them to overcome ethical challenges. They can link the researchers with other ethics experts who might be able to provide specialised guidance on complex topics.

To capitalize on the opportunity to inquire, engage and educate, the compliance officer must have a certain level of expertise in research ethics and an investment of resources and time which goes beyond that required to carry out the perfunctory "box ticking" exercise to which compliance is often relegated. With that investment, however, the research project or institution can make full use of the opportunity that the compliance officer position avails.

References:

Stahl BC, Akintoye S, Fothergill BT, Guerrero M, Knight W and Ulricane I (2019) Beyond Research Ethics: Dialogues in Neuro-ICT Research. *Frontiers in Human Neuroscience* 13:105. <https://doi.org/10.3389/fnhum.2019.00105>

Equality and Diversity – the Approach of the Human Brain Project (HBP)

Karin Grasenick (CONVELOP) and Pilar Flores Romero (Polytechnical University Madrid)

Introduction

The Human Brain Project (HBP) is an interdisciplinary project, involving among others neuroscience, medical informatics, AI, robotics and ensuring that ethical, social, and philosophical issues are an integral part of brain research and the infrastructure provided (Salles et al., 2019). Important ingredients for successful interdisciplinary collaboration are equal opportunities, diversity, inclusion (EDI) which if considered well not only contribute to fairness and individual career development, but also to science and innovation by combining various perspectives, heuristics, and methodological approaches. European funded projects must therefore outline how equal opportunities are considered, with a clear focus on gender. Accordingly, the HBP foresaw a dedicated task and searched for strategically advice, design, and coordinate gender equality measures and to measures to integrate diversity dimensions in research via an open call.

The approach developed by CONVELOP, who joined the HBP in 2018, builds upon research from Change and Complexity Management as well as Gender Studies and Sociology to acknowledge the complexity of the project. It has been cocreated and documented in two consequently Gender Action Plans (GAP). The second GAP II (2021)³⁴ is based on the experiences with implementing this first Gender Action Plan I (2019)³⁵ which are summarised in the GAP Implementation Report³⁶ as well as on reflecting on the specific challenges that a complex, large scale science project faces. It outlines the activities for diversity and equal opportunities in a so called logic chart, how necessary inputs are expected to lead to outputs (short term results) and outcomes (long term impacts) in following four areas of intervention:

1. Cocreate a project specific vision and opportunities to constantly communicate the content.
2. Analyse structure and processes to recommend the integration of gender/diversity aspects.
3. Demonstrate how the diversity dimensions can be considered in scientific research content.
4. Support individuals, teams, leaders, to build their capacities towards gender equality, diversity, and inclusion.



Figure 2 – Illustration of the GAP in the HBP (Source: Karin Grasenick, CONVELOP)

³⁴ Read the second Gender Action Plan (GAP) here: <https://zenodo.org/record/5535670#.ZAXkph-ZNhE>

³⁵ Read the first Gender Action Plan (GAP) here: <https://zenodo.org/record/5535662#.ZAbvDh-ZNhE>

³⁶ Read the GAP implementation report here: <https://zenodo.org/record/5535676#.ZAXk7h-ZNhE>



The four areas are interrelated, which can be exemplified as follows:

Based on the analysis of structures and procedures the former gender advisor committee was designed as diversity and equal opportunities committee (DEOC) to become an advisory body to the Project Coordination Office (PCO) and Directorate (DIR) of the project. The DEOC is composed of HBP board members, leaders, scientist, technologists and managers engaged in the work for the HBP from different domains. It can be considered as a ‘microcosm’ of the HBP, consisting of diverse project members of different genders, scientific backgrounds, nationalities, ages, career stages, etc. to consider different perspectives and experiences when working for equal opportunities. The committee provided advice and feedback on the GAP and on all activities planned. It had a regular flow of communication and meetings, submitted quarterly reports for the DIR (Directorate) and was invited as guest to SIB (Scientific and Infrastructure Board) meetings. The DEOC members communicated key messages in their work packages and support the implementation of the measures and activities.

One of the measures in area three, focusing on diversity in research content was the diversity in research paper award (DIRPA), suggested by CONVELOP and cocreated in its details with DEOC. The DIRPA honours excellent scientific achievements which consider diversity traits especially in neuroscience and related fields. Examples are the relevance of sex/gender differences for neuro-degenerative diseases or analyses and correction of biases reproduced by AI applications based on the data they are trained with. The DIRPA was first launched at the HBP Summit in Athens, Feb. 2020. Additionally, the HBP has developed guidelines and webinars to encourage and support scientists to integrate diversity traits in research design, conclusions and representation of results which has been proven to contribute to innovative insights. In line with these developments, the DEOC Chairs presented the call, its relevance, available HBP guidelines and further background information on DEOC itself at the virtual HBP Summit 2021, DEOC members actively promoted the call in their networks, thereby contributing to area one, the constant communication. The DIRPA winners were presented in a webinar with further keynote speakers, results made available online together with further guiding materials thus contributing to area 4, capacity building³⁷. The criteria, overall process and the results were presented to DIR and SIB, encouraging reflection and further usage of the materials provided.

All measures of the GAP were designed with an inclusive approach. For example, the HBP High Potential Mentoring Programme supported both women and men regardless of career stage or their professional role within the HBP. Especially managers in science are often women holding a master’s degree or PhD. Matching of mentoring partnerships were based on application forms in which mentees and mentors could amongst others indicate their preferences in terms of gender, professional and life experiences in general. The mentoring programme benefitted from the virtual setting (Grasenick et al., 2022). Applying to a virtual mentoring programme offers the opportunity to broaden the perspective with a mentoring partnership across different disciplinary backgrounds, country or research performing organization. Virtual training, coaching and guiding materials accompanied the mentoring programme and supported capacity building³⁸. It was time-efficient since no travel or physical meetings were required. The feedback was overwhelmingly positive. Participants emphasized the importance of understanding each other to overcome gender biases and to share responsibilities and collaborate fairly.

The inclusive approach highlights gender in its intersectionality with further diversity dimensions such as race, age, or socioeconomic, cultural and scientific backgrounds. And allowed the HBP to play a pioneering

³⁷ Find the materials here: www.edi-toolkit.org/research

³⁸ Read more on the programme here: <https://www.humanbrainproject.eu/en/about-hbp/diversity-and-equal-opportunities/measures-and-materials/>



role in advancing gender equality by improving the gender balance of scientists in leadership positions from 16% in Sept. 2017 to 36% in January 2022. These figures demonstrate that the HBP approach is successful. The reference model to evaluate the representation of women is a **cascade model** (Kleinberger-Piere et al., 2020):

1. Women and men are expected to be represented at each career level in the same proportion.
2. Initial figures derived at the level of PhD students and Postdocs, based on ratios from sources like the European SHE FIGURES, and/or organisations considered as best practice for each Work Package or Task.
3. Reasons for any significant differences are checked by leaders. If discrimination, the HBP will look for a solution.
4. The reference model was discussed and signed by the Science Infrastructure Board (SIB) of the HBP in 2019 with additional commitment from leaders at all levels of the HBP in the form of letters of personal commitment and development of HBP guidelines.

Materials that support EDI oriented governance and research in future projects and infrastructures were summarised as an EDI Toolkit³⁹. It is designed for everyday usage by offering (i) basic information, (ii) guiding questions to develop a governance framework and (iii) research content (iv) quick checklists, (v) as well as measures to support leadership, talent, and events. It offers support to establish standards for interactions, engagement, and decision-making.

Conclusions

Stakeholders responsible for setting up strategies and measures for EDI on a project level must be aware that within the partnership most likely perceptions, experiences, and competences in relation to EDI will be heterogeneous. Perspectives will differ depending on disciplinary and professional background, ethnicity, gender, age etc. For international partnerships strategies and measures in place will differ from country to country and in each RPO. If project members want to collaborate across various RPOs or even countries, they need to engage in a dialogue on what EDI principles they agree on how they should be implemented.

The co-creation of a vision on what can be achieved together in this specific project will support a shared understanding and commitment. The co-creation process ideally involves the variety of project stakeholders to integrate the diverse perspectives and experiences right from the start. Measures that striving for an inclusive or “universal” design aim to be accessible and binding for all stakeholders rather than for specific groups only (REFERENCE A. Steward and V. Valian, 2018). Such universal designs allow various stakeholders to identify will the goals, to discover similarities with others and will enhance commitment and mutual support.

PIs must apply appropriate procedures, ensure transparency, and carefully reflect and counteract the effects of potential biases in a highly competitive environment. Procedures that contribute to the effectiveness of collaboration are also an excellent opportunity to support the practical implementation of EDI principles, for example by providing questions for reflections, easy to follow guidelines for participatory discussions and decision making, work distributions or research design, tools that can be used in daily project tasks – from governance to research - support awareness and implementation. This is especially relevant if the number of stakeholders exceed team size or if due to the duration of the project staff fluctuation during runtime is to be expected. By supporting integration across distances and different disciplines project identity and cohesion can be strengthened.

³⁹ Please find the toolkit here: <https://www.edi-toolkit.org/>

References

- Grasenick, Karin; Sarah Beranek, Anne-Sophie Godfroy, Sybille Reidl, Pilar Flores Romero, Helene Schiffbänker, Johanna Stadlbauer, Julia Trattnig, Andrea Wolffram, Christine Wächter (2022, May). The Gendered Analog-Digital Divide in Virtual Academia. In Conference Proceedings of the STS Conference Graz 2022 (p. 93).
- Kleinberger-Pierer, Magdalena; Pohn-Weidinger, Simon; Grasenick, Karin (2020) Fair projects - bad data? Evaluating the gender balance in science projects. fteval Journal for Research and Technology Policy Evaluation (50). pp. 60-71. ISSN 1726-6629
- Arleen Salles, Jan G. Bjaalie, Kathinka Evers, Michele Farisco, B. Tyr Fothergill, Manuel Guerrero, Hannah Maslen, Jeffrey Muller, Tony Prescott, Bernd C. Stahl, Henrik Walter, Karl Zilles, Katrin Amunts, The Human Brain Project: Responsible Brain Research for the Benefit of Society, Neuron, Volume 101, Issue 3, 2019, Pages 380-384, ISSN 0896-6273, <https://doi.org/10.1016/j.neuron.2019.01.005>.
- Abigail J. Stewart Abigail and Virginia Valian (2018) An Inclusive Academy. Achieving Diversity and Excellence. The MIT Press (ISBN 9780262037846)



Charting a New Path: Addressing Dual Use Issues Beyond Legal Compliance

Inga Ulinicane (De Montfort University)

Introduction

Dual use has been one of the key topics that the HBP Ethics and Society team has advanced. Through broad-ranging collaborations, we have developed a novel approach to dual use and misuse issues. As any project funded by the European Union's Framework Programme, the HBP must comply with the Framework Programme regulation that all its work should have an exclusive focus on civil applications. Accordingly, the HBP is not permitted to work on military applications. This rule sets the HBP apart from other brain initiatives, some of which are funded by defence funding (Ulinicane, 2020).

Dual Use Opinion

However, in this area, the HBP has gone well beyond legal compliance, which is based on traditional understanding of dual use as military-civilian dichotomy. Recognizing importance of dual use and misuse issues for emerging neurosciences and neurotechnologies, the Ethics and Society team developed an Opinion on Dual Use. This involved various activities over several years including research, public engagement, consultations, and workshops with HBP researchers and external experts. These activities have been well received by dual-use experts who, for example, saw a webinar organised by the HBP as "a first promising step in the direction of awareness-enhancing strategies" (Ienca et al., 2018).

Insights from these activities led to our Opinion on Responsible Dual Use, which was published in 2018. In this Opinion, we suggest a broader approach to dual use of concern considering political, security, intelligence, and military uses of concern. According to the Opinion, dual-use of concern refers to:

"Neuroscience research and technological innovations, and brain inspired developments in information and communication technologies, for use in the political, security, intelligence and military domains, which are either directly of concern because of their potential for use in ways that threaten the peace, health, safety, security and well-being of citizens, or are undertaken without responsible regard to such potential uses (Aicardi et al., 2018: 5)."

We recognise that the identification of research of concern is far from straightforward and will remain a matter of debate. Such a debate draws on Responsible Research and Innovation (RRI) approach and uses AREA (anticipation, reflection, engagement, and action) framework to facilitate identification and tackling of any potential concerns.

HBP Dual Use Working Group

To follow-up on the Opinion, the HBP Directorate established a project wide Dual Use Working Group (DUWG) and gave it a mandate to prepare and implement dual use activities⁴⁰. In its work, the DUWG collaborates with many colleagues within and outside the HBP (Ulinicane et al., 2022). Most importantly, work of the DUWG is closely linked to the Ethics Rapporteur programme. Most of the DUWG members are Ethics Rapporteurs and dual use of concern and misuse is one of the questions they reflect on in their one-pagers of ethical issues. To support this reflection, the DUWG provides training activities such as webinars. Regular meetings of the DUWG – once every two months – serve as 'a safe space' where any concerns can be raised

⁴⁰ Read more about the HBP activities on dual use here: <https://www.humanbrainproject.eu/en/science-development/ethics-and-society/dual-use/>

and discussed. Ongoing meetings and discussions help to develop common vocabulary, shared understandings and learn from each other. This is very important, considering diversity of the group members (neuroscientists, computer scientists, engineers, managers etc) and challenge of reflecting on potential uses and concerns early on, as a lot of HBP work is fundamental research.

Moreover, the DUWG is closely linked to and interacts with other HBP structures such as the Data Governance Working Group on access policy and the HBP Education Programme on training activities. Regular workshops on dual use and misuse at the HBP Student Conferences and Young Researchers events have showed that students are very interested not only in dual use and misuse questions but also in broader ethical and social aspects of their research. Our webinars and training events have attracted interest beyond the HBP. We have been invited to provide training and advice on dual use issues for another Framework Programme project. These diverse activities have been important for addressing various goals from raising awareness and developing sensitivity towards potential concerns to changing research culture.

Dual use is challenging topic theoretically and practically. To go beyond legal compliance that requires exclusive focus on civil applications and consider a broader range of concerns, we have found three lessons particularly important (Ulnicane et al., 2022). First, to address this complex question, it is important to combine research and practice. In developing and following up on our broader approach to dual use of concern, we have drawn on our research on governance of emerging technologies, Responsible Research and Innovation and dual use. On the other hand, our practical engagement has raised new questions for future research. Second, it is important to continuously undertake closely interrelated activities of anticipation, reflection, engagement, and action. They should not be treated as a linear process with separate stages but rather as complementary and interdependent activities. Third, in developing and pursuing a novel approach to dual use, it is important to continuously experiment, learn and have a dialogue addressing and reflecting on emerging issues. Instead of ticking boxes, it is important to have an ongoing conversation and attention to new questions that might emerge, as brain research develops.

References

- Aicardi, Christine, Bitsch, Lise, Bang Bådum, Nicklas, Datta, Saheli, Evers, Kathinka, Farisco, Michele, Fothergill, Tyr, Giordano, James, Harris, Emma, Jørgensen, Marie Louise, Klüver, Lars, Mahfoud, Tara, Rainey, Stephen, Riisgaard, Karen, Rose, Nikolas, Salles, Arleen, Stahl, Bernd, and Ulnicane, Inga. 2018. "Opinion on 'Responsible Dual Use' Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology." Zenodo. <https://doi.org/10.5281/zenodo.4588601>
- Ienca, Marcello, Fabrice Jotterand, and Bernice S. Elger. 2018. "From Healthcare to Warfare and Reverse: How Should We Regulate Dual-Use Neurotechnology?" *Neuron* 97 (2): 269–74. <https://doi.org/10.1016/j.neuron.2017.12.017>.
- 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>
- Ulnicane, Inga, Tara Mahfoud and Arleen Salles. 2022. Experimentation, learning, and dialogue: an RRI-inspired approach to dual-use of concern. *Journal of Responsible Innovation*. <https://doi.org/10.1080/23299460.2022.2094071>



The Human Brain Project's Opinion on Trust and Transparency in Artificial Intelligence (AI)

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Introduction

Trust and transparency are central themes in the ethical debate around the design, deployment and governance of AI. Lack of transparency of AI systems, untrustworthy outcomes of AI applications, and possibilities that AI can lead to harm for societies, specific groups and individuals are key challenges to the use of AI, that can undermine public trust and pose threats to fundamental freedoms, collective safety and human rights.

To address these and other issues, the HBPs' Ethics and Society Team, with the support of a group of AI researchers from the HBP, started in 2019 to produce its Opinion on Trust and Transparency in Artificial Intelligence⁴¹, that was published in 2021.

Drawing on insights from social science and humanities research, including a series of webinars, consultations and workshops with citizens, policy makers, scientists and other stakeholders, the Opinion aimed to explore the key challenges and issues around transparency, trust and trustworthiness in AI research and innovation, and the responsibilities that arise from these for researchers and innovators in the HBP and the AI scientific community more broadly.

The Opinion highlights areas where challenges to the development of trustworthy, accountable, and transparent AI applications have become apparent in recent years, including in the context of commercialization, international technology transfer, dual use innovation, misuse or premature applications, the emerging of potential adverse effects, challenges to democratic freedoms, rights and decision making, as well as with regard to gender equality, diversity and inclusion.

Based on this research, the Opinion has prepared six recommendations for the Human Brain Project, that have aimed to provide guidance on how the HBP can address some of the identified issues, and to inform further inter-disciplinary research, awareness creation, and educational activities in relation to the social, ethical, and regulatory dimensions of AI, in the final phase of the HBP and the transition to EBRAINS.

The final three of these recommendations set out a research agenda to address key questions around the ethical and social challenges of the exploitation and commercialization of AI-related research outcomes, tools, and technologies in the HBP, as well as international technology transfer and collaborations with research organizations and companies in the EU and overseas.

These issues have been explored further in the context of interviews, a survey among AI researchers in the HBP, and a workshop on November 7, 2022⁴², that investigated the social, ethical, conceptual, and philosophical dimensions of brain-inspired AI and robotics applications, which has led to recommendations for HBP researchers and EBRAINS⁴³.

⁴¹ Please find the opinion here: <https://zenodo.org/record/4588648#.ZA7mHx-ZPb1>

⁴² Read more about the workshop here: <https://www.humanbrainproject.eu/en/about-hbp/news/events/5557/wp3-ebrains-joint-workshop-technology-transfer-commercialization-and-ipr-practical-ethical-and-governance-challenges-in-the-transition-to-a-post-hbp-future>

⁴³ The recommendations can be read here: <https://drive.ebrains.eu/f/62777c397d6d4f0a8a31/>



Capacity Building on Responsible Research and Innovation in the Human Brain Project (HBP) & EBRAINS

George Ogoh (De Montfort University)

Introduction

Throughout the years of the Human Brain Project (HBP), much work has been done by the Ethics and Society team - a multidisciplinary group of ethics experts – to promote Responsible Research and Innovation (RRI) to all stakeholders of the HBP and EBRAINS. On the one hand, some of the activities focused on raising awareness that a project as complex as the HBP has the potential of raising ethical issues and societal concerns which must be addressed to enable societal acceptability of the processes and outcomes of the project. On the other, it sought to build capacities for identifying and addressing the relevant issues and concerns. To these ends, different methods and fora have been used to enable reflection and action on such issues including participation at internal and external events such as workshops and conferences, and membership of working groups both within and outside of the project (for example working groups in the International Brain Initiative - IBI). In this section, an extensive RRI capacity-building programme is described to highlight some of the outcomes of the exercise and recommendations for EBRAINS in this area.

The Capacity Building Programme for RRI in the HBP and EBRAINS

In April 2020 with the EBRAINS infrastructure opening to the wider society, it was considered necessary to begin a dedicated RRI capacity-building programme to further help institutionalise RRI (Stahl et al., 2021) among users and developers of the infrastructure. Although the Capacity Building programme was initially developed for HBP researchers and EBRAINS users, it has increasingly been opened to the broader society by advertising training events publicly using social media, blog posts etc and through online curation of training resource activities. That way, even after the work of the Ethics and Society team ends at the culmination of the project, responsible research practices and good technology development processes can continue in EBRAINS and ensure that its outcomes are ethically acceptable, societally desirable, and sustainable.

A total of 17 modules were developed on RRI-related topics and themes that are of high relevance for the HBP and EBRAINS. Along with an introductory module on RRI, the broad array of topics addressed in the capacity building programme include the following: neuroethics, data governance, dual use and misuse, public and stakeholder engagement, foresight and anticipation of social and ethical issues, diversity and inclusion in research, researcher integrity and awareness, as well as ethics and RRI dimensions of Knowledge transfer and commercialisation⁴⁴.

The modules developed on these topics build on previous experiences of the HBP Ethics and Society team in providing RRI educational resources using several methods and formats of delivery. Also, some were the result of an integration of existing RRI-related structures and the activities of groups like the HBP Dual Use Working Group, Data Governance Working Group (DGWG) and committees like the Diversity and Equal Opportunities Committee (DEOC). And in keeping with the dialogical approach to ethics (Stahl et al, 2019) that the Ethics and Society team adopted for engaging with stakeholders throughout the project, a substantial portion of each training involved open dialogues to encourage reflection among participants on the ethics and responsible innovation issues of activities of the project.

⁴⁴ Many of these training resources and information for future events can be found online at: <https://www.humanbrainproject.eu/en/social-ethical-reflective/about/capacity-development>.

Highlights of the RRI Capacity Building Programme

The RRI capacity-building exercise has largely been received well by the target audience. This can be seen in the encouraging numbers of participants attending the capacity-building events and the positive feedback received at the end of each event. For example, in terms of attendance, although the total target number of attendees for these events was set at 150, this value was exceeded by 70% up to 6 months before the expected end date of active delivery of training. With regards to feedback received, although only about half the participants at the training events often responded to feedback surveys, over 90% of responses indicated a good level of satisfaction. For example, for the Diversity and Inclusion in Research modules, participants describe the training using expressions like ‘excellent’, ‘successful’ and ‘productive’. Similarly, in describing their level of satisfaction, participants in the Introductory RRI and data governance modules used words like ‘extremely satisfied’ or ‘very satisfied’.

It is, nevertheless, important to highlight that the training events also presented an opportunity for the training providers to learn both through the feedback provided by the participants as well as the dialogical processes of engagement at events. To derive maximum benefit from both the feedback provided via anonymous surveys at the end of training and the dialogic feedback offered at discussion sessions, the trainers positioned themselves as equal partners in learning rather than adopting a ‘know-it-all’ posture. Considering that everyone at these events has varying levels of awareness of the ethical issues of the project including how to identify and address them effectively, such an approach was useful in enabling all parties involved to benefit from the session. Thus, the trainers not only got a better insight into the ethical issues of the research and other activities within the project and EBRAINS but also a better understanding of how to improve the training sessions. For, example at one of the sessions, it was suggested that rather than centre the discussion around multiple case studies, it might be more beneficial to focus on one to enable a more in-depth discussion around particular topics that the participants find most relevant. This suggestion was then fed into subsequent deliveries and thus enabling a more satisfactory outcome.

Recommendations

The Ethics and Society team would not be around to continue to deliver a dedicated RRI capacity-building programme for EBRAINS beyond the end of the Commission Horizon2020 funding period. It is however important that opportunities are created for all users of the infrastructure to benefit from the extensive resources created for RRI capacity building as this can help to institutionalise responsible research practices and outcomes among its users.

As noted by Stahl et al. (2019) “researchers face many pressures on their time and prolonged exchange about the ethical issues presented by their research may not be a high priority” and there is the additional challenge that some have the view that topics on research ethics or RRI are not a high priority. Therefore, effort has been put towards creating an online repository of training resources created for the RRI capacity-building programme. However, it would be difficult for future users of EBRAINS to find these resources, understand their relevance or engage them without being provided relevant pointers or compelled to do so. It is therefore recommended these resources are curated on EBRAINS in such a way as to make them easily findable by the infrastructure users, and suitable means are employed to compel them to engage with relevant resources. However, appropriate care must be taken, so that actions taken to compel users to engage with such training resources do not encounter similar debates as those on ‘ethics policing’ or ethics washing.

References

- Stahl, B.C. et al. (2019) Beyond Research Ethics: Dialogues in Neuro-ICT Research. *Frontiers in Human Neuroscience*, 13, [Online] Available from: <https://www.frontiersin.org/articles/10.3389/fnhum.2019.00105>
- Stahl, B.C. et al. (2021) From Responsible Research and Innovation to responsibility by design. *Journal of Responsible Innovation*, [Online] Available from: <https://www.tandfonline.com/doi/abs/10.1080/23299460.2021.1955613>

The Task Force on Implementation of Responsible Research and Innovation in EBRAINS

Amal Matar (Uppsala University)

In 2020, the leadership of Responsible Research and Innovation (RRI) in the Human Brain Project (HBP), took the initiative to form a task force on the implementation of RRI in EBRAINS. The Task Force was formed in the early months of 2021. It was entrusted to pass on the long experience gained in responsible research and innovation (RRI) during the HBP to the newly forming Research Infrastructure (RI) of EBRAINS. To ensure representation of the wide varying backgrounds and expertise within the HBP, the TF members were selected from different scientific, humanities and social sciences disciplines as well as from the management.

Through regular meetings the members discussed the suitable ways to ensure aspects of RRI and societal considerations are fulfilled in the new RI. The first undertaking was creating an ethics and society vision for EBRAINS. With the engagement of the HBP community and local and international stakeholders from civil societies, public engagement professionals, diversity experts and neuroscientific and RRI professionals, EBRAINS' vision was shaped⁴⁵, and ultimately adopted by EBRAINS and its Board of Directors (BoD).

Ensuring excellent science goes beyond drafting an inclusive vision, it entails implementing structures and policies that enact ethical and professional standards within an organisation. This was recognised by the TF and the EBRAINS BoD. The TF therefore contributed to draft the outlines of an EBRAINS' Ethics & Society Committee (EESC). The Committee would have a central role in guiding and advising EBRAINS on achievement so of the EBRAINS Ethics and Society Vision, and on proactively engaging with ethical and societal issues related to the research infrastructure and its activities.

Among the many issues that need to be addressed, one is data governance. As a RI, EBRAINS uses, shares, and processes various types of data including animals and human data among both European and non-European partners. To ensure harmonisation and ethical governance of data, different options are under consideration. For example, ensuring that an expert in ethical governance of data is on board the EESC. In addition, EBRAINS AISBL is looking for opportunities to realise the EBRAINS Ethics and Society Vision and its RRI elements, to ensure that EBRAINS research contributes to societal benefit and mental and brain health.

⁴⁵ The EBRAINS Ethics and Society Vision can be read here, and one can also find more information on the composition of the task force: <https://ebrains.eu/ethics-and-society-vision/>

Tailoring Communication to Different Audiences

Josepine Fernow (Uppsala University)

Introduction

All collaborations rely on good communication, and the benefits of developing a skill set for researchers to raise awareness and generate interest in their work seems self-evident. But there is another objective behind integrating a focus on communications in an RRI work package in a big European project. In practice, Responsible Research and Innovation (RRI) relies on communicating *good practice*: to peers, policy makers and end users. Always with the objective to generate buy-in for approaches and uptake of different practices across the Human Brain Project (HBP), in EBRAINS and beyond. That requires us to be able to get our messages across disciplinary and professional borders, from one expert to the expert in another field, the generalist, research manager, patient advocate, or 'lay' person.

New demands require new skills

There is an increasing demand from the European Union and other funding agencies that researchers show how their efforts have impact. This demands that we develop new (or different) skills, where researchers need to design strategy and measure and evaluate their contribution to both science and society. In the final phase of the HBP, science communication was added to the RRI, with the aim to work proactively to strengthen the communication of the ethics and society efforts in the Human Brain Project to audiences inside the project, in EBRAINS, in the larger scientific community and beyond. This effort had a clear objective: raising awareness of the RRI & reflective approaches in the HBP, generating interest in our work, and supporting buy-in and uptake of good practice.

Using an iterative approach

In the last three years of the Human Brain Project, the RRI task has worked to implement strategies to support this objective. Although led by communications professionals, this has been a joint effort: everyone involved in ethics and society tasks across the project has been involved in a process to develop impact objectives, communication objectives and communication tools and tactics to support those objectives. The approach is both strategic and operational, using our own ethics and society channels on Twitter and the Ethics Dialogues blog, the main Human Brain Project channels, and Uppsala University's Ethics Blog. The approach is iterative, monitoring and evaluating progress indicators for social media and Altmetric data for publications to measure the effectiveness of communications, and using citations as indicators of scientific impact. Constantly monitoring and re-evaluating communication tactics, always with the aim to support buy-in and uptake of results.

Building capacity for cross-disciplinary communications

The aim is to facilitate cross-disciplinary and cross-professional communication, and at the core is a capacity building effort. Starting out, training on communication was offered everyone involved in RRI work in the HBP. This training later became a module in the capacity building efforts for EBRAINS users, training people across the project in how to communicate their research questions and results to wider audiences. The training sends an important message for scientists to take a good look at their own view of the public. Sometimes, scientists look at the 'the public' as a homogenous group of non-experts, or perhaps overlapping (but still homogenous) groups of 'lay people' that lack knowledge (Besley & Nisbet, 2013). However, the 'public' is an abstract and heterogenous collective, made up by everyone in society, including the scientists

themselves (Condit, 2001 & Burns et al., 2003). In the training, we show how this collective can be divided into a series of overlapping publics (Burns et al., 2003).

This means that also within the HBP, we are communicating our expertise to lay audiences. And that the same principles we use to talk to ‘the public’ can support us in cross-disciplinary and cross-professional collaborations: raising awareness of what we do, generating interest in the approaches, and developing buy-in through joint activities and research outputs. At the end of the project, what we can show is a set of key performance indicators to evaluate the reach and engagement with the content that we have shared through project channels. However, the real impact is yet to become visible: developing capacity among the HBP’s Ethics & Society community to connect communication objectives to impact, and understand how raising awareness of issues can generate interest in results, supporting buy-in to, and uptake of, the RRI practices and approaches developed in the HBP over the last decade.

Note: This text develops some of the ideas in a note on achieving impact (some arguments for designing a communications strategy) by Josepine Fernow, published as part of Declich, A. et al, RRI Implementation in bioscience organisations: Guidelines from the STARBIOS2 project from 2019 (<http://uu.diva-portal.org/smash/get/diva2:1396179/FULLTEXT01.pdf>).

References

- Besley, J.C., & Nisbet, M.C. (2013). How scientists view the public, the media and the political process. *Public Understanding of Science*, 22(6), 644– 659. <https://doi.org/10.1177/0963662511418743>
- Burns, T.W., O'Connor, D.J., & Stocklmayer, S.M. (2003). Science communication: A contemporary definition. *Public Understanding of Science*, 12(2), 183–202 • <https://doi.org/10.1177/09636625030122004>
- Condit, C. (2001). What is “public opinion” about genetics? *Nature*, 2(10). <https://doi.org/10.1038/35093580>

Some Thoughts on Advising on Ethics in the Human Brain Project (HBP)

Berit Bringedal (The Institute for Studies of the Medical Profession), Markus Christen (University of Zürich) and Josep Domingo-Ferrer (University of Rovira i Virgili)

Introduction

Within this essay, we, as three of the members of the first two Ethical Legal and Social Aspects (ELSA)/Ethics Advisory Board (EAB) committees of the Human Brain Project (HBP), provide a summary of our reflections on our work. We describe what we did and briefly discuss its impact.⁴⁶

The Ethics advisory boards were appointed at the onset of the Human Brain Project (HBP) in 2014. Evidently, the HBP leaders recognised the significance of attention to ethical issue – while also separating research ethics questions (REC) from the general ethical, legal, and social aspects (ELSA). This led to the establishment of two committees, ELSA with 9 members and REC with 6. The members were selected to represent relevant aspects of the research in the HBP, as well as holding competencies in ethics, legal and social aspects.

The mandates of the committees were rather unspecific, apart from a general expectation to advising the HBP Board of Directors on ethical, regulatory, social, and philosophical issues raised by the research in the HBP. Thus, the first period of work of the committees was spent on discussing what's and how's. This "finding phase" reflected the difficulty of establishing ethics oversight of "big neuroscience". Up till then, neuroscientific research was usually performed in smaller units that mainly had to comply to standard ethics research procedures, such as obtaining consent from local committees with respect to, say, animal research standards, or to securing proper informed consent of research participants. More general ethical aspects of neuroscience were discussed in a distinct, but still young, field called "neuroethics" - that established itself in the early 2000s.

Furthermore, experiences from similar committees were few, since most ethics work deals with smaller projects, be it in research ethics, clinical ethics, or ethics in public health, or public policy in general. The size of this project, the multidisciplinary research, the multidisciplinary competency of the members of the committee, the lack of a concrete mandate, and the fact that none of the members had expertise in all the project's research topics, initiated a period of groping efforts to define our work.

From two committees to one

A key insight of this first searching process was that the separation into two different domains of ethical advice – research ethics on the one hand and the broader ELSA perspective on the other – was unfortunate, for two reasons. First, the research ethics committee was legally superfluous with respect to the standard procedures of research ethics that still relied on local and national guidelines and laws. Research ethics was required in the development of the local/national research protocols, and local RECs were involved in this. Thus, the role of a REC in the HBP was not only unclear, but also superfluous.

Second, "big neuroscience" raised new questions, such as sharing large-scale data sets, ethical challenges tied to organizational structures, or the dealing with legislative frameworks that are in tension with each other. Such questions could not be adequately addressed by applying the traditional separation between ELSA and research ethics. Because of these considerations, the committees were merged in 2015 into the

⁴⁶ In writing this comment, we relied on the more extensive publications by Bringedal et al. (2016) and Christen et al. (2016) that were published during the active phase of the committees.

Ethics Advisory Board (EAB), and the number of members significantly reduced (from 15 to 9 members). This EAB is still working to date, although its membership was substantially renewed in 2020.

The new EAB focused on identifying the features that make the HBP "special" with respect to ethical challenges (see Box). An important insight here was that "classical" ethical issues discussed in neuroethics, or research ethics more generally, were of less importance compared to aspects that could be subsumed as "organizational ethics" issues, related e.g. to the distribution of responsibility in large projects, the management of data and information, or to counter the tendency that such projects are "too big to fail", which may generate a problematic incentive to not addressing organizational ethics issues.

Features of HBP posing potential ethical challenges

(based on Bringedal et al. 2016)

- Size and Organisation
- Distribution of responsibility
- Optimism bias
- Exaggerated expectations
- Concentration of funding
- Too big to fail
- Data origin and Ddata storage
- Informed consent procedures
- Information flow
- Role of EAB and of ethics management
- Communication between EAB and the scientists
- Communication between EAB and the management

Eventually, we decided to focus on how ELSA-challenges could be identified and dealt with through the establishment of structural systems to identify such issues. Information sharing and risk assessment systems are crucial, especially in projects as big as the HBP.

We discussed the following challenges and principles to guide our work (Bringedal et al. 2016):

- Identify potential high-risk areas (where are the red lights?)
- Perform risk assessments that include weighing of benefit and harm
- Streamline information and decision routes
- Attribute clear responsibility
- Include all stakeholders in information sharing (e.g. through internet sites)
- Ensure regular external ethical reviews (EAB members present in the discussions with PIs)
- Ensure that the data origin is always declared
- Declare conflict of interest as routine for all scientists and decision makers and other stakeholders (including EAB members)
- Establish data protection systems
- Create a system for communication between the EAB and scientists
- Enforce transparency measures: All is public unless there are important reasons against. In that case, the reason giving should be public and explicit

In our view, the establishment of structures for information sharing and channels where concerns could be expressed was a success. They were both necessary conditions to improve the ethics of research, as well as the use of research. (For a description of the structures, see Bringedal et al 2016.)

However, although necessary conditions, they were not sufficient. Among other issues, it was problematic for a reduced number of volunteers, as the members of the people were, to keep abreast of all activities that



were potentially sensitive in terms of ethics. For one thing, the EAB lacked a global view of all personal data being collected by the different HBP teams, and the flow of such data. A similar limitation was faced for several other ethics issues, such as consent, health, safety, or risks connected to the use of technological innovations. In the end, the EAB had to limit its scope to the higher-level issues that were submitted to the committee by the coordinators and team leaders of HBP.

We also think that some of the above-mentioned features of the project represent challenges that we did not find effective systems to deal with. Both the “too big to fail” problem and the “optimism bias”, which are inherent in many large projects, were hard to address and mitigate. The tendency towards overselling what a project can accomplish in order to compete for scarce funding, might also involve a tendency towards overselling what the ethics initiatives/work can accomplish. This is probably valid both for the aims of the external ethics committees and for the work of the Ethics and Society subproject.

Technological projects may pose some particular challenges in terms of putting ethics high on the agenda. The technological scientific disciplines are not, traditionally, much concerned with ethical or social implications of their research fields. This represents an extra barrier in communications between ethicists and researchers, as well as in the individual researcher's attention to potential ethical issues.

The EAB contributed to establishing structures which were able to meet the need to deal with some of the ethical concerns attached to the project (such as a system for registration of concerns, or the appointment of an ombudsperson). We contributed also to making sure that at least one researcher in every subproject was specifically designated to focus on ethical issues, as well as to inform and collaborate with the members of the EAB. However, we did not find ways to address other pressing challenges, for reasons described above.

Lessons learned

The scope of this paper does not allow anything close to a comprehensive discussion of the barriers, nor their implications. However, we will draw a few general lessons. **First**, the task of an ethics committee should be worked out in more specific detail before the onset of the project, and the appointment of the members of the committee. This does not, or should not, exclude the possibility and responsibility of the ethics committee to focus on other issues, or develop their own systems for dealing with them – but prevents a waste of time in the beginning of their work. Ideally, the work with ethics should be as prepared as the scientific work, in terms of e.g. a well prepared protocol, by experts in ELSA.

Secondly, although there are reasons to avoid payment of the members of ethics committees, we think the volunteer model entails the risk that the work is deprioritised by committee members. The ethics advisors' independence is important, but independency can be upheld even if the advisors receive payment. To this aspect, we will add that the possibility to publish scientific papers on the topics that arise during their work can also be viewed as a motivator by the committee members. This publication task should also be independent of the research project, to help preserve the committee's independence.

Finally, we think that modesty is called for, in terms of the scientific aims and the tasks of the ethics committees. Paying attention to, say, the social implications of the use of technological innovations, is clearly important. Adding this to the responsibility of an ethics committee may, however, risks doing more harm than good. The task is probably too big to be reasonably dealt with within such committees, and it involves high opportunity costs.

References

- Bringedal B, Christen M, Biller-Andorno N, Matzusaki H, Rabano A: "Strangers" in neuroscientific research. On being advisors for ethical, legal, social, and philosophical aspects of the Human Brain Project. In: Leefman J (ed): The Human Sciences after the Decade of the Brain. Elsevier 2016
- Christen M, Biller-Andorno N, Bringedal B, Grimes K, Savulescu J, Walter H: Ethical challenges of simulation-driven big neuroscience. American Journal of Bioethics Neuroscience. Vol 7, Issue 1, 2016.

Perspectives from outside the Human Brain Project

On February 2, 2023, the responsible research and innovation group of the HBP organised the conference “The future of responsible brain research”⁴⁷. With the conference, the team wanted to reflect on the status of RRI in general and as a vehicle for future brain research. The conference saw presentations from a diverse group of distinguished scholars, and community leaders working with brain research. We are grateful to present their reflections from the conference here.

Towards a Deliberative Governance of Human Brain Research and Innovation

Rene von Schomberg (Aachen University)

Introduction

The Human Brain Project eventually had a governance which included a *responsible research and innovation approach*, going beyond the state of the art in this area, by among other, taking a discursive approach to the normative and ethical issues raised by the project⁴⁸. This is applaudable and certainly contributed to a more *responsible research* approach, however, the relationship with *responsible innovation* is yet to be (better) addressed. I will make below, following a short analysis, here a proposal for governing the innovation dimension in a more responsible way, consistent with my original idea of Responsible Innovation. It is also coherent with the RRI approach taken by the partners who worked on this subject matter under the HBP.

The Human Brain has been an object of technological interventions by medical devices for a long time. Among other, Electroconvulsive Therapy (which we used to call ‘Electroshock’) was first employed in Italy in 1938, and for the first time regulated as a medical device in 1976 by the US Food and Drug Administration. There has been only a first discussion at the regulatory level to require a pre-market approval for this type of medical device in 2011. We must appreciate that even though there is a lot of medical data on the impact of electroconvulsive therapy on patients, we have little knowledge, if not outright ignorance of the underlying principles and mechanics of its operation. This is also true for virtual all other medical devices employed on the brain of patients. Whether it concerns electroconvulsive therapy or, for example, cranial electrotherapy stimulation (first employed in 1794, with up to date, even *no clear* advantages of its use), deep brain stimulation or other types of neurostimulation. We can thus conclude that we have employed innovations without knowing what we are exactly doing. Although we have overcome the belief, held till deep in the Renaissance period that we can cure madness by extracting a stone out of the skull of patients (put on paint by Jan Steen, most of the time in an ironical context, late 17th century), we might still be closer to this historical period in terms of ignorance what we are exactly doing to our patients with our current medical devices, than we dare to admit (Figure 3).

⁴⁷ Programme and speakers can be found by following the link on the Human Brain Project’s website: <https://www.humanbrainproject.eu/en/about-hbp/news/events/5809/the-future-of-responsible-brain-research>

⁴⁸ Berd Carsten Stahl *et al* (2019), Front. Hum. Neurosci., 29 March 2019, Sec. Cognitive Neuroscience

Volume 13 - 2019 | <https://doi.org/10.3389/fnhum.2019.00105>



*Figure 3- The extraction of the stone of madness'
or 'Cure of the Folly', painted circa 1670 by Jan
Steen (1626-1679). (Rotterdam: Museum
Boymans-Van Beuningen).*

This (at least partial ignorance) of how our devices work is matched with an equal lack of knowledge of the functioning of the human brain as such. This constituted in fact a reasonable motivation to launch the HBP. Now the HBP eventually embraced scientists who anticipate different interpretations of what the immense amount of data the HBP produced will eventually mean for our understanding of the human, we miss an oversight of the status of epistemic debate on this matter. I propose to provide a mapping of this debate and a transdisciplinary assessment of the quality of knowledge produced, including an assessment which research directions might be fruitful in the future. Such a type of knowledge assessment would certainly help to counterbalance possible one-sided criticism of the HBP such as the recent article of Emily Mullin in the MIT review⁴⁹ that no new knowledge is produced at all. Important for such a knowledge assessment is to sort out what type of HBP data might generate new knowledge of the functioning of the Human Brain. On the point of production of *new* knowledge, external observers might be disappointed, notably since the HBP was donated with the largest public grant a European Commission funded project ever received (slightly over 1 billion EUR). However, a knowledge assessment procedure could signal to the broader scientific community at what front our understanding has improved and in which direction further research might be promising. This might be well practised along the facilitation of the infrastructure EBRAINS⁵⁰, a platform that hopefully will feature all the HBP data produced in open science mode, e.g., accessible, and re-usable to all scientists across nations and scientific disciplines, to perform further research.

We will continue to conduct both research and innovate in a context of high uncertainty and significant ignorance of how to understand the human brain and its functions. Nonetheless, this fact hasn't stopped research funders around the world to engage industry in the hope to establish technological leadership in this field. The Harvard Geneticist George Church, one of the leading scientists behind the *US Brain initiative* stated, 'Like the Human Genome Project a decade earlier the brain project would lead to "entirely new industries and commercial ventures" (cited by Mullin, see footnote 2). The European Human Brain Project equally had the objective to include and facilitate *industrial* researchers. An Innovation and Technology Transfer Node which is part of the HBP will, among other, facilitate commercial exploitation. The node seems to operate on the classical innovation policy basis that any innovation which has commercial potential must be stimulated. Responsible Innovation, however, requires giving *directionality* to innovation, e.g., as I (and equally also all the colleagues who worked on responsible research and innovation within the HBP) stated it, e.g., to drive innovation towards socially desirable ends.

⁴⁹ Emily Mullin, *MIT Technology Review*, 25 August 2021:
<https://www.technologyreview.com/2021/08/25/1032133/big-science-human-brain-failure/>

⁵⁰ Visit EBRAINS: <https://ebrains.eu>

I fear that an open infrastructure with data that can be exploited by industry, might lead to a flurry of new medical devices for brain stimulation, or other brain interventions, without that knowing what these devices will do to our brains. In those cases, we might even have less public knowledge of the impacts of these devices than in the case of Electroconvulsive Therapy, since the algorithmic processing of brain recordings and brain data may well be privatised, and thus inaccessible for verification or understanding by other researchers and regulators. This privatisation will also jeopardize the collective knowledge production, a public funded project is supposed to deliver. Premarket approval of those devices would need to be required by regulators, although industrial organisations (like in the case with 'electroshock') will unlikely favour this, given the costs for testing and their fear for being outcompeted by pharmaceutical companies who aim at cures for the same diseases as possible new medical devices. What can a socially desirable, commercial exploitable outcome based on privatised algorithmic processing of brain data then look like? How are we going to balance the promotion of pharmaceutical approaches with the promotion of medical devices?

This all points towards a *lack of* innovation governance both in a regulatory sense and in research for innovation sense, rather than even stating the possibility of how a responsible governance could look like.

A plea for a code of conduct for industrial organisations employing HBP data.

Policy development treads a fine line: governments should not make the mistake of responding too early to a technology, and failing to adequately address its nature, or of acting too late, and thereby missing the opportunity to intervene. A good governance approach, then, might be one which allows flexibility in responding to new developments.

While in the absence of a clear consensus on how we can get a better understanding of the functioning of the human brain, and although there continues to be significant scientific uncertainty on the nature of the risks involved when it comes to the application of medical devices, good governance will have to go beyond policy making focused on legislative action. The power of governments is arguably limited by their dependence on the insights and cooperation of societal actors when it comes to the governance of new technologies: the development of a code of conduct, then, is one of their few options for intervening in a timely and responsible manner.

Similarly, legislators are dependent on scientists' proactive involvement in communicating possible risks and must steer clear of any legislative actions which might restrict scientific communication and reporting on risk. The ideal is a situation in which all the actors involved communicate and collaborate. The philosophy for an appropriate code of conduct is precisely to support and promote active and inclusive governance and communication. It assigns responsibilities to actors beyond governments and promotes these actors' active involvement against the backdrop of a set of basic and widely shared principles of governance and ethics. Through codes of conduct, governments can allocate tasks and roles to all actors involved in technological development, thereby organising collective responsibility for the field. Codes of conduct can be efficient by supporting various parties to play their roles in the overall eco system of innovation, encourage partnerships, and facilitate mechanisms for interactions and conflict solving. Such a code of conduct could also constitute a roadmap towards a form of collective IPR, whereby an RRI approach would be part of the licensing arrangements.

Outlook: Deliberative Approaches to the Policy Making Process

Deliberative approaches to brain research and innovation should not be reduced to an exercise in public debate. While such debate is important, the responsible development of medical devices also requires deliberative approaches to technology assessments. Scientific and public controversies often remain inconclusive when there is a lack of consensus on the normative (ethical) basis of such assessment

mechanisms. In the development of medical devices for brain interventions, there is not yet a shared understanding of how we might define the acceptability of possible risks, or of how we would weigh them against possible benefits or alternative medical interventions. Moreover, in the context of scientific uncertainty and production of knowledge by a range of different actors, we need knowledge assessment mechanisms which will assess the quality of available knowledge for the policy process. A deliberative approach to the policy-making process would complement and connect with deliberative mechanisms outside policy. The outcomes of ongoing knowledge assessment should feed into other assessment mechanisms and into deliberation on the acceptability of risk, the choice of regulatory frameworks or the measures taken under those frameworks. Knowledge assessment following the result of foresight exercises would then be important tools in setting out arguments for the necessity and nature of possible future legislative actions. Currently I see a procedural gap, especially, when it comes to the identification of knowledge gaps and the assessment of the quality of the available knowledge. Responsible Research and Innovation cannot fully be addressed at the level of projects but must sit in the broader governance of the eco-system of innovation.

In the meantime, in terms of funding large research efforts, we have made significant progress in thinking on how we need to (re-)organise the research and innovations process. Whereas the HBP was still by large a tech and data-driven research project from its conception, the current societal-mission oriented research projects under Horizon Europe (2021-2027) promise to (mandatory) include essential RRI principles, such as co-design and co-creation of (open science) research and innovation by stakeholders and citizens whereby the stakeholders are committed to social objectives, not technological objectives per se, featuring the employment of foresight, citizen engagement and feedback to public policies. Although the theory behind the funding of mission-oriented research has improved, its success will, by large, depend on the capacity to understand and practice research and innovation in RRI fashion. Unfortunately, there are up till now little signs to make productive and systematic use of the RRI capacities produced over the last decade (Gerber et al., 2020).

References

Alexander Gerber, Ellen-Marie Forsberg, Clare Shelley-Egan, Rosa Arias, Stephanie Daimer, Gordon Dalton, Ana Belén Cristóbal, Marion Dreyer, Erich Griessler, Ralf Lindner, Gema Revuelta, Andrea Riccio & Norbert Steinhaus (2020) Joint declaration on mainstreaming RRI across Horizon Europe, *Journal of Responsible Innovation*, 7:3, 708-711, DOI: 10.1080/23299460.2020.1764837

Local Engagement and Global Reciprocity at the Frontiers of Neuroscience

Judy Illes (Neuroethics Canada, Division of Neurology, Department of Medicine, University of British Columbia)⁵¹

Introduction

I share my thoughts here on responsible neuroscience by focusing on four points: 1. building on the past, 2. expanding international discourse and collaboration, 3. keeping the goal of remediating the burden of neurologic and psychiatric disease and expanding access to innovations for treatment as key priorities, and 4. committing to guidance that is calibrated to evidence and the commensurate with the mission of the sciences.

I approach these points with the benefit of looking through two complementary lenses: a career-long commitment to responsible innovation spanning the full continuum of R&D in neuroscience from cells to systems; and as new chair of the International Brain Initiative (IBI)⁵² since the fall of 2022. The overarching theme that brings the four points together and the convergence of the lenses is the importance of both local engagement and global reciprocity.

Building on the past: As all who attended the February 2nd, 2023, Human Brain Project’s “The Future of Responsible Brain Research” conference were likely aware, the neuroethics train left the station in 2001 and has been running at high speed since then. Neuroethics has been devoted to the responsible innovation mission since the formalisation of the field and is built on the foundation of work in other disciplines including bioethics, law, psychology, sociology, and philosophy. The importance, efficiencies, and respect of building on past work and not reinventing the wheel is the core of my first point: there is a great deal to learn from those who shoulder successes and failures of the past, and the opportunities thus created for each step neuroethicists take in research – large or small – into the future.

International discourse and collaboration: The OECD meeting on responsible innovation for neurotechnology in Shanghai, China, in 2018 demonstrated that there is a global commitment to the goal of responsible innovation (*OECD, 2019. Recommendation of the Council on Responsible Innovation in Neurotechnology, Paris*). It is incumbent on each participating nation to undertake steps to respond to the joint call issued at the meeting in a way that meets, first, the values and priorities of local cultures, socio-political climate, and research environment. Local uptake is essential for public trust, funding, and relevant policy-making. These form the pipeline to global reciprocity; without buy-in on the ground level, global engagement will be thin and unsustainable.

Local engagement and global reciprocity are thus key themes for the IBI, its signature programs, and the unique nature of global neuroscience itself. Seven nations now form an active IBI, and we are exploring new partners for the consortium. We are unpacking challenges at hand through dedicated Working Groups that have been active for more than five years as well as new ones. Working Groups focused on Tools and Technology Dissemination, Data Standards and Sharing, Training and Outreach have been producing regional and international events since the formation of the IBI in 2017. A special focus on early career researchers (ECRs) is a priority for the Canadian Brain Research Strategy (Ménard et al., 2021). This year, the IBI benefits from a refreshed Neuroethics Working Group that is being transformed to fill gaps such as neuroethical

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⁵² Visit the IBI here: <https://www.internationalbraininitiative.org/>

considerations for health economic impact and gender and diversity, not yet or barely touched by the discipline to date (please see also the contribution by A. Salles above). Also new are Working Groups on the Emotional Brain, Brain Mapping, and Crosscultural Perspectives (Perreault et al., 2022). The Working Group structure enables topic areas to be addressed in a systematic and rigorous way, through both linear unidirectionally and multidirectional communication. The IBI welcomes ideas for new Working Groups from member nations and their collaborators. The vision for global neuroscience is bold; the fundamental principles of open collaboration and cooperation are driving forces.

Focus on brain and mental health: As scholars and scientists interested in ethics in and for neuroscience, we have an obligation not only to offer evidence and provide the support to apply it, but to mitigate hype that sometimes thinking and talking about ethical concerns engenders. This is becoming an increasingly acute problem as the news and journalistic media are focusing increasingly on topics such as mind reading, mind control, and liberty of mind. The excitement and even anxiety around the future of mind reading and modulation are legitimate, but disproportionate distractions and deflections from still critically needed efforts to remediate, suffering and promote brain health and well-being is a looming risk. Until just access for all people, including those living in poverty or faced with food and water insecurity, historically marginalised populations, and those facing the ravages of climate change and war are solved or mitigated, futuristic ambitions ought to take second place in a conversation that largely relies on interventions intended for medicine.

Calibrations of guidance: As neuroscience must act responsibly, so must scholars and scientists act as offerors of guidance. We must resist the temptation to overstate, overclaim, overpromise, or over create codes of conduct and regulations. Ethics deliverables must be served by data, embrace the diverse voices and experiences of all people, be practical, and modelled in the positive behaviours to which moral societies subscribe.

In summary, ethics is an empowering force for science *writ large*. For neuroscience, neuroethics has been a force for enabling a dip into the exploration of all that makes humans and animals sentient beings in a world that is defined by both regional and cultural distinctiveness. With other visionary endeavours in neuroscience, it has enabled and highlighted the opportunity to leverage a growing if not unprecedented global appetite for inclusive engagement, communication, and interaction.

Note: The views in this contribution are of the author alone.

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References

Ménard, C., Siddiqui, T.J., Sargin, D., De Koninck, Y., Illes, J. The Canadian Brain Research Strategy: A focus on early career investigators, Canadian Journal of Neurological Sciences, 2021, 00: Can J Neurol Sci. 2021; 00: 1-3.
doi:10.1017/cjn.2021.81

Perreault, M., Gabel, C., King, M., Mushquash, C., Ménard, C., Young, J., De Koninck, Y., Illes, J. An Indigenous lens on priorities for the Canadian Brain Research Strategy, CJNS. 2022, 1–3: doi:10.1017/cjn.2021.501.

Hurdles and Strategies for Neuroethics Integration

Karen Rommelfanger (Institute of Neuroethics Think and Do Tank)

Introduction

Interdisciplinary collaboration is especially critical in the brain sciences because the assumptions, values, and meaning of findings in brain science are deeply complex and culturally informed. This complexity has significant implications for how brain research is designed, conducted, understood, and translated into the real world (GNS Delegates et al, 2018).

We and others have identified this real-world translation of neuroscience research and implementation of interdisciplinary work as a largely unmet challenge and opportunity for neuroethics (Wexler and Specker Sullivan, 2021, Dankowsky, 2022). Still, there is much we have learned from the work of the international brain initiatives.

One context for our learning is via the US BRAIN Initiative and its National Institutes of Health (NIH) driven neuroethics efforts to generate a neuroethics roadmap (NIH, 2019) for research as well as to develop mechanisms for creating more collaborative communities of neuroethicists and neuroscientists. A second context is through the Global Neuroethics Working Group (GNWG) of the International Brain Initiative (IBI), where we explored more deeply - in our convenings and virtual community conversations - what the necessary conditions might be to making inclusive, culturally aware collaborations possible⁵³.

While great strides have been made to establish new robust networks for collaboration through exemplars such as in the Human Brain Project (HBP) and other partners in the IBI (Rommelfanger et al, 2019; Quaglio et al, 2021), several challenges remain. I discuss three of them.

First and foremost, most if, not all, of the challenges noted below seem to revolve around the need to create a shared understanding of the value proposition for working together. For example, scientists who conceptualise neuroethics in limited ways, such as synonymous with compliance, will miss the opportunity to scope and deepen their work on fundamental neuroscience concepts. Ethicists who fail to understand the reality of science may offer work that not only is irrelevant, but also contributes to hype. Still, the unclear added value for some is reflected in the limited human and financial resources allocated to do this kind of collaborative work.

To be clear, there are organizations that appreciate the value proposition of interdisciplinarity, like many of the large brain projects and other programs offered by the European Research Area Networks⁵⁴ and the re-invigorated support by the Dana Foundation through its new leadership⁵⁵.

Even so, many organisations struggle to create agreed upon impact metrics for the positive effects of interdisciplinary work like pursuing neuroethics integration. And so, specifically for traditional funding mechanisms, supporting interdisciplinary integration may be difficult in the absence of those metrics. For interdisciplinary work, impact metrics will likely need to move beyond the traditional peer-reviewed papers (Ravenscroft et al, 2017), and instead focus more on metrics of cultural and community change and measures of new practices in how science is designed, carried out, and disseminated.

⁵³ See more about the GNWG here: <https://globalneuroethicssummit.com>

⁵⁴ See more here: <https://www.era-learn.eu/network-information/networks/era-net-neuron-ii/ethical-legal-and-social-aspects-elsa-of>

⁵⁵ Learn more about the Dana Foundation programmes and actions here: <https://dana.org/about-dana/>



A second challenge is the need to enhance communication among interdisciplinary groups like neuroscientists and neuroethicists (Das et al, 2022). One important step toward meeting this challenge will necessarily be the development of education and training programs. Effective programs must be co-developed through interdisciplinary collaborations to build mutual understandings of topics like neuroethics and the state of the art in neuroscience. Part of this educational experience will require greater dedication to promoting communication and exchange amongst interdisciplinary and international expertise. What we've learned through our Global Neuroethics Working Group-Round Tables is that it's not just the formal opportunities to conduct research projects together that are important, but also the informal coffee breaks and physical proximity to each other as humans, that facilitates trust building and idea incubation for collaborations. These informal interactions can do heavy lifting toward building a new culture, but also require intentional facilitation.

The third challenge is the need for greater incentivisation or, perhaps, the creation of new structures of incentivisation. This is intimately connected to the lack of clear value proposition and lack of dedicated spaces for community building. Here, a critical step will be to engage the entrenched ideology and infrastructures that prevent curiosity, humility, and recognition of valuable interdisciplinary work. Dedicated funding certainly is a helpful top-down mechanism for driving interdisciplinary collaboration, but shifts in internal mechanisms are also needed, such as offering tenure and promotion based on participating in interdisciplinary collaborations, and other formal ways to celebrate exemplars in the space. In this way, individuals may feel less isolated and more courageous about embarking on interdisciplinary work. Another note on funding, is that the funding structure must be mindful to not promote that some experts be seen as subservient to others, which can feel like the case, for example, when an ethicist is funded under the work of a fixed scientific agenda.

To these three challenges, I offer five recommendations for overcoming them:

- Raise awareness about assumptions and limited understandings of the expertise of others.
- Make time for intentional processes of collaboration in multidisciplinary groups.
- Be intentional and aware of styles of communicating and bias in conceptualization of terms that are informed by discipline and worldviews.
- Advocate for societal actors so that they can have capacity to implement neuroethics and avoid orientations where some experts are subservient to others.
- Work to cultivate cultural change, from infrastructure to community building.

These recommendations, along with an attempt to cultivate humility, openness, reflexivity, intellectual agility, creativity, cultural curiosity, can hopefully lead to a more productive collaboration that truly leverages the collective wisdom of the group (Das et al., 2022).

While I am certain that there have been struggles, the HBP, having woven neuroscience and neuroethics and philosophy into a shared infrastructure at its inception, has been an important exemplar for the greater neuroscience ecosystem. The scientific community is looking forward to how the learnings of the HBP Ethics and Society work will be woven into EBRAINS⁵⁶. Beyond the basic research community, there will need to be new bridges for these values and practices to be shared across not only geographies and disciplines, but also across sectors, where the greatest translation to society will likely be seen. The need to particularly engage in cross-sectoral conversation has risen from many international policy entities in the context of

⁵⁶ Read more about EBRAINS: <https://ebrains.eu/>

neurotechnology innovation (Pfotenhauer et al, 2021; UNESCO IBC, 2021) and represents a significant area of focus for the Institute of Neuroethics Think and Do Tank⁵⁷.

Ultimately, the shift we need to see is a culture of science where neuroscientific excellence is not separate from humanistic inquiry of fundamental concepts and broader societal implications, and where diverse methodologies can be reciprocally informed to create outputs that are more aligned and relevant for greater public good (Taylor and Rommelfanger, 2022; Robinson et al, 2022).

References

- Dankowsky, J, 25 March 2022, audio podcast, ScienceFriday, National Public Radio, <https://www.sciencefriday.com/segments/brain-science-ethics/>
- 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
- 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.
- NIH Advisory Committee to the Director (ACD) Working Group on BRAIN 2.0 Neuroethics Subgroup (BNS). The BRAIN Initiative and Neuroethics: Enabling and Enhancing Neuroscience Advances for Society Oct. 2019
- Pfotenhauer, S. M. et al. Mobilizing the Private Sector for Responsible Innovation in Neurotechnology. *Nat. Biotechnol.* 39, 661–664 (June 2021).
- Quaglio G, Toia P, Moser EI, Karapiperis T, Amunts K, Okabe S, Poo MM, Rah JC, Koninck Y, Ngai J, Richards L, Bjaalie JG. The International Brain Initiative: enabling collaborative science. *Lancet Neurol*. 2021 Dec;20(12):985-986. doi: 10.1016/S1474-4422(21)00389-6. PMID: 34800415.
- Robinson JT, Rommelfanger KS, Anikeeva PO, Etienne A, French J, Gelinas J, Grover P, Picard R. Building a culture of responsible neurotech: Neuroethics as socio-technical challenges. *Neuron*. 2022 Jul 6;110(13):2057-2062. doi: 10.1016/j.neuron.2022.05.005. Epub 2022 Jun 6. PMID: 35671759.
- Rommelfanger KS, Jeong SJ, Montojo C, Zirlinger M. Neuroethics: Think Global. *Neuron*. 2019 Feb 6;101(3):363-364. doi: 10.1016/j.neuron.2019.01.041. PMID: 30731058.
- Taylor L, Rommelfanger KS. Mitigating white Western individualistic bias and creating more inclusive neuroscience. *Nat Rev Neurosci*. 2022 Jul;23(7):389-390. doi: 10.1038/s41583-022-00602-8. PMID: 35585252.
- UNESCO International Bioethics Committee. Report of the International Bioethics Committee of UNESCO (IBC) on the Ethical Issues of Neurotechnology Dec. 2021
- Wexler A, Specker Sullivan L. Translational Neuroethics: A Vision for a More Integrated, Inclusive, and Impactful Field. *AJOB Neurosci*. 2021 Dec 1:1-12. doi: 10.1080/21507740.2021.2001078. Epub ahead of print. PMID: 34851808; PMCID: PMC9187971.

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