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Authors:	Jean-Pierre CHANGEUX, IP (P29) Kathinka EVERS, UU (P82) Benjamin SIMMENAUER, IP (P29)		
Compiling Editors:			
Contributors:	Nikolas ROSE, KCL (P32) Bernd Carsten STAHL, DMU (P11) Abdul MOHAMMED, LNU (P35) Kevin GRIMES, KI (P31) Yadin DUDAI, WIS (P78) Lars KLÜVER, FT (P16) Lise BITSCH, FT (P16) Mark SHAW, DMU (P11) Shamim PATEL, LNU (P35)		
STO Review:	UHEI (P45): Björn KINDLER, Sabine SCHNEIDER, Martina SCHMALHOLZ		
Editorial Review:	EPFL (P1): Richard WALKER, Guy WILLIS, Lauren ORWIN		
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1 Executive Summary

The HBP is committed to upholding and implementing the principles of Responsible Research and Innovation (RRI) in all its research and development. Subproject (SP) 12 is the hub of RRI in the Human Brain Project (HBP). It undertakes Foresight research on social, ethical, legal and cultural implications of HBP research (WP12.1), explores conceptual and philosophical issues and challenges raised by HBP research (WP12.2), engages HBP researchers with external stakeholders and the general public (WP12.3), builds awareness and capacity for social and ethical reflection among HBP researchers (WP12.4), and supports the robust management of ethical issues of the HBP as a whole (WP12.5). This report describes the activities of the HBP Ethics and Society Programme for the first 18 months, and summarises early results from SP12 Work Packages (WPs).

In WP12.1, Foresight research highlighted two main questions; that of data protection and privacy, and that of disease signatures and the “personalisation” of medical interventions for psychiatry and neurological disorders. WP12.1 developed a series of scenarios relating to these questions. Each scenario hypothesised the Medical Informatics Platform (MIP) achieving its objectives to a different degree, explored the problems that might be faced in implementing its objectives, and suggested possible public and stakeholder responses. WP12.1 then organised further events where HBP scientists and stakeholders met to discuss these scenarios, and comment on any new concerns. The scenarios were also used to stimulate discussion at a one-day seminar on Future Medicine, held in Copenhagen on 9 October 2014. The first report on Future Medicine (D12.1.1) was prepared on the basis of this research, and the evidence that WP12.1 had generated. A number of key “emerging challenges” were identified, and WP12.1 formulated a series of 18 recommendations to address these issues.

WP12.2 has developed conceptual and philosophical works on four different topics:

- The concept of simulation: WP12.2 proposed a comprehensive practical taxonomy of simulation, and placed the goals of computer brain simulation within it.
- The relationships between brain knowledge, simulation and the human mind: WP12.2 defined different conceptual obstacles relating the potential explanatory power of large-scale brain simulations. The notion of epistemic opacity, and issues related to mental illness simulation, were of particular interest.
- Brain knowledge and consciousness disorders: WP12.2 scrutinised the numerous ethical issues raised by the neurotechnological assessment of residual consciousness in disorder of consciousness (DOC) patients. The role of brain simulation in studies of consciousness, and in communication with patients, is still at the proof of concept stage. However, the theoretical possibility of its application strongly urges continued reflection on its possible clinical use.
- The brain’s social contexts: WP12.2 worked on cultural imprinting on brain architecture, especially through the concept of “epigenetic rules”. It also started working on the consequences human brain simulation could have on the meanings of “human identity” and “personal identity”.

WP12.3 started the dialogue program with both external experts and stakeholders, and with the general public. The Stakeholders Forum organised by WP12.3 taught SP8 researchers about the privacy issues at stake in their plans to build a multi-level data federation structure. The main results of the various meetings and seminars organised by *Fonden Teknologirådet* (the Danish Board of Technology Foundation [FT - P16]), in collaboration with other SP12 Partners and SP8, gave rise to a list of recommendations. These were made available in a newsletter published in December 2014. SP8 has decided to go ahead with the recommendation to implement a privacy impact assessment (PIA), as stated in the HBP’s first response to the Ethics Review. Engagement activities with the general public have also started; the first online consultation took place in Month (M) 20 (instead of M18 as planned). It gathered a sample of more than 100 French citizens, who expressed their perceptions, expectations and questions relating to general topics concerning HBP Future Medicine. These included the



definition of psychiatric and mental diseases, current and future ways to cure them, and big data and data sharing. They also responded to a non-technical presentation of two key aspects of the SP8 platform, as identified by other groups in SP12 (the data integration strategy plan and brain disease signature plan).

WP12.4 conducted a series of interviews with SP Leaders. It also initiated a survey of HBP researchers' ethical and social views, and also examined the researchers' perceptions of RRI in their areas of expertise. The main outcome of the interviews with SP Leaders was a list of ethical themes, i.e. issues that raised questions about the duties, roles, or moral, legal or professional status of HBP stakeholders. The following major ethical themes have been discussed, and were translated into questions in the survey: data protection and individual privacy; governance of data provided to the shared platforms; prevention of abuse of shared platforms; the appropriate use of animal experimentation and development of common standards; research integrity, including the maintenance of scientific diversity through collaboration; intellectual property; the appropriate use of medical and robotic applications; communication with the wider neuroscience community and communication with the public and other stakeholders.

WP12.5 supported the Ethical, Legal and Social Aspects committee's (ELSA) three semi-annual meetings, and the Research Ethics Committee's (REC) five quarterly meetings. The HBP Summit in Heidelberg was a lesson for both committees. For ELSA, it presented little opportunity for its members to enter the ethical discourse, since they were meeting for only the second time. At the same time, REC had a heavy workload due to animal and human research institutional review board (IRB) approvals, and had yet to examine non-IRB tasks, such as robotics and Dual Use. WP12.5 directed itself primarily to collecting the information needed to ensure procedural ethics were enforced. The data registry was adequate for collecting documentation attesting IRB approval for projects involving animal or human research. However, the collection of materials to help the ethics committees understand issues in areas outside the traditional IRB scheme was not adequate. For instance, non-EU research could not rest on the local IRB, and WP12.5 would have to provide a mechanism to help the committees establish the ethical propriety of those Project proposals. The two committees displayed different trajectories; ELSA was less concretely engaged than REC, and REC wanted to share the core competencies of ELSA. The criticisms were followed by recommendations for a merger, which the committees agreed in Geneva on 26 March 2015. The committees proposed 13-15 members to form a new committee, the Ethics Advisory Board (EAB), which would meet three times yearly.

2 Introduction

From M16 to M18, SP12 devoted much time and effort to revising the approach towards ethics governance for the Operational Phase. This drew on the experience gained during the Ramp-Up Phase, and the evaluation by ethical and technical reviewers in M16. Parts of this revised governance structure will be implemented during the remaining months of the Ramp-Up Phase.

The first action was the establishment of an SP12 Steering Committee, which is dedicated to the day-to-day running of SP12. This consists of the leaders of each WP in SP12. The Steering Committee is now responsible for defining SP12 principles and management practices; Standard Operating Procedures; coordinating, monitoring and documenting HBP action on ethics-related issues; responding to requests for ethics-related documentation from EC officials and reviewers; and facilitating the collaboration of SP10 WPs with one another, with other HBP SPs, with stakeholders and with members of the public.

The SP12 Steering Committee has met via weekly videoconferences, and has worked on the following topics:

- Definition of the role of a new ethics committee: Ethics Advisory Board

- Definition of the role of an HBP Ethics Manager
- Writing of the SP10 and Ethics sections of the FPA
- Partial restructuring of SP12 activities and possible merge of WP12.4 and WP12.5.

This extensive work has forced the SP12 team to postpone the submission of Deliverable D12.6.3 to M19, and the team responsible for T12.3.1 to postpone the achievement of the Milestone 222 (first online debate).

2.1 Aim of this Document

This report will describe the activities of the HBP Ethics and Society Programme. It will also summarise early results from foresight studies (WP12.1), studies of ethical and philosophical issues (WP12.2), and the public awareness and researcher awareness programmes (WP12.3 and WP12.4), and describe the activities of the governance and regulation work package (WP12.5). The report will include the first conference papers published by members of the group. Detailed results from the Foresight Lab will be published in separate reports designed for the general public (see WP12.1).

2.2 Society and Ethics: Responsible Research and Innovation in the HBP

The HBP is committed to upholding and implementing the principles of RRI in all its research and development. Its overall approach has four interlinked phases: anticipation (of future implications, based on research), reflection (activities to enhance ethical and social awareness and reflection among HBP researchers), engagement (engaging, disseminating and debating HBP research with stakeholders and the general public), action (ensuring the results of these activities help shape the direction of the HBP itself, in ethically robust ways that serve the public interest). RRI will be implemented through the collaborative work of the five SP12 Ethics and Society WPs.

3 Foresight Studies

3.1 Goals and Nature of the Activities

WP12.1 (King's College London [KCL, P32]) aims to evaluate the social, ethical, legal and economic consequences for Europe that arise from new knowledge and technologies created by the HBP. To do this, WP12.1 established the HBP Foresight Lab (T12.1.1), which conducts systematic foresight exercises to identify and evaluate these potential impacts. In the Ramp-Up Phase, it focuses on the three major themes of the HBP, and will deliver a Foresight Report for each of them: Foresight Report on Future Medicine (D12.1.1), Foresight Report on Future Neuroscience (D12.1.2) and Foresight Report on Future Computing/Robotics (D12.1.3).

In the first few months of the Project, WP12.1 reached each of the Milestones set out in the Description of Work; KCL outlined activities (MS213) and defined methods (MS214), and the team has been implementing them in order for research to progress. The precise research methods used have been developed to correspond to specific areas of investigation. The first topic was Future Medicine, and the Foresight Report on Future Medicine was delivered on time, at the end of M18 (March 2015). It focused on the work of the SP8 MIP, and in particular on its aim to “federate” clinical data from patients with psychiatric and neurological diseases. This data would come from hospitals and research sites in Europe and elsewhere, and would be “mined” in the hope of identifying “brain signatures” of disorders. These could, in the long term, inform “personalised medicine”.



WP12.1 undertook a series of research activities from M1 to M18. It conducted extensive research on relevant literature, including previous reports from ethics and related bodies in various European countries, and many discussions with key experts. WP12.1 also co-organised webinars, seminars, and workshops with a variety of stakeholders. These aimed to establish expert views, understand the responses and concerns of civil society organisations, and develop an evidence base for analysing likely implications of developments in medical informatics over the next five to ten years.

To facilitate this work, WP12.1 developed productive collaborations with all SP12 WPs, in particular with T12.3.3 (FT) and with WP12.4, (De Montfort University [P11]). WP12.1 contributed suggestions and feedback to their task, and provided KCL with ideas and material content for task T12.1.1 in return. For example, the interviews conducted by WP12.4 (Researcher Awareness) provided data on ethical and social perceptions among the HBP researchers. In addition, to ensure integration and maximise collaboration within SP12, a number of the stakeholder consultation activities were organised together with WP12.3 (T12.3.3), and in particular with P16, FT. For example, a joint webinar with SP8 researchers and non-HBP scientists and stakeholders was held in May 2014. This focused on multi-level brain data federation and protection and the development of “disease signatures” and personalised medicine.

This research highlighted two main questions; that of data protection and privacy, and that of disease signatures and the “personalisation” of medical interventions for psychiatry and neurological disorders. Consequently, WP12.1 developed a series of scenarios relating to these questions. Each scenario hypothesised the MIP achieving its objectives to a different degree, explored the problems that might be faced in implementing its objectives, and suggested possible public and stakeholder responses. WP12.1 then organised further events where HBP scientists and stakeholders met to discuss these scenarios, and comment on any new concerns. The scenarios were also used to stimulate discussion at the one-day seminar on Future Medicine, held in Copenhagen on 9 October 2014.

3.2 Main Outcomes of the First Foresight Studies

The first report on Future Medicine was prepared on the basis of this research, and the evidence that WP12.1 had generated. The report identified two key areas where social, legal and ethical questions arose. The first area concerns the issues surrounding data protection and data privacy that must be considered when accessing and analysing patient records, and the second concerns the nature and consequences of searching for the brain-based signatures of psychiatric and neurodegenerative diseases, and using these in personalised medicine. A number of key “emerging challenges” were identified, and WP12.1 formulated a series of 18 recommendations to address these issues.

3.2.1 Data Federation and Privacy

Data protection and data privacy present major challenges for the federated organisation of the MIP, which the foresight research suggested would be key to the future of the Project. WP12.1 identified three such challenges that are interwoven in the multi-layered architecture of the MIP: legality, trustworthiness and privacy. Some of these may be addressed by technology management measures; others by developing community building activities around the MIP, which include not only clinicians, the pharmaceutical industry and other professional stakeholders, but also patient groups and diverse publics.

On the basis of this work, and on discussions with MIP directors and researchers, WP12.1 therefore made the following recommendations:

- 1) Undertake regular and systematic work on scenarios for misuse.
- 2) Establish an Information Security Architecture partnering Project, to be established before the end of the Ramp-Up Phase, which would preferably be extended to the whole HBP if such a provision is not already in place.



- 3) Complete a Privacy Impact Assessment.
- 4) Evaluate consent requirements for different MIP functions, with a focus on informed consent wherever appropriate.
- 5) Consider special issues that may arise from the use of data acquired from outside the European Union (EU).
- 6) Establish protocols for engaging patients, patient support and stakeholder groups in respect of the MIP's different functions.
- 7) Establish a Public Engagement and Research Dissemination Plan.
- 8) Create a Data Governance Committee for the MIP, with a broad membership including representatives from Users and the public.
- 9) Establish a research audit structure that can identify, authorise and audit all MIP users.

3.2.2 Disease Signatures and Personalised Medicine

Interpreting complex biological and clinical data to identify signatures that may be clinically useful brings many challenges. Further challenges arise if such signatures are used to identify predispositions or susceptibilities to disorder. These challenges include recognising and interpreting statistical clusters within data, identifying when a particular biological signature is an indicator for disease, translating findings into protocols and guidelines for clinical practice, ensuring that clinicians and patients use disease signatures appropriately, and preparing the regulatory and governance infrastructure for what is often termed “personalised” or “precision” medicine. Many of these can only adequately be addressed by strong consultation and engagement with affected communities.

Thus, on the basis of our foresight work on disease signatures, WP12.1 made the following recommendations. These will ensure that an effective partnership is created with patients, clinicians and other potential users of disease signatures:

- 1) Include patients and clinicians in a research advisory capacity.
- 2) Address implications for clinical practice, in particular by engaging clinicians in the assessment and verification of disease signatures, and their use in clinical applications.
- 3) Address implications of disease signatures on clinical ethics.
- 4) Reflect on the use of brain signatures in identifying pre-clinical susceptibilities.
- 5) Ensure awareness that differences in brain structure or function do not equal brain disease.
- 6) Develop effective communication strategies to explain the potential clinical and research uses of brain signatures to the Public and other audiences.
- 7) Link with other research communities and relevant regulators to develop appropriate pathways for translating research into clinical applications.
- 8) Consider the wider implications of moving to a brain-based understanding of disorders.
- 9) Consider how the future use of findings to generate employment and wealth creation may affect public trust in, and support of, the HBP.

Some of these recommendations have already been incorporated into the developing structure and processes of the MIP. Others will require action as the work of the HBP develops. The report will be widely disseminated within and outside the HBP. WP12.1 will work with other SP12 WPs, and with other HBP members, to ensure that full consideration is given to implementing our recommendations. These collaborations embody and enact the principles of Responsible Research and Innovation, and together aim to ensure that the HBP's work is directed to meet the major challenges psychiatric and neurological disorders pose to individuals, families, communities and societies.



WP12.1 has already started work on the second theme of task T12.1.1, Future Neuroscience. It is currently organising activities that will lead to drafting the second foresight report, in particular a scoping workshop in the domain of future neuroscience, to be held in M21. In addition, KCL participated in the webinar, “Dual Use and Neuroscience—An Online Debate on Current Developments” in M13, organised by T12.3.3. Professor Nikolas Rose facilitated the informational discussions, and WP12.1 is collaborating on further on-going work in this key area.

4 Studies of Conceptual and Philosophical Issues

Work Package 12.2 examines the philosophical and conceptual bases and implications of HBP research, with a special emphasis on how a unified and multilevel understanding of the human brain might give insights into the human mind. The task of WP12.2 is the identification, articulation, analysis and critical assessment of relevant conceptual issues. Many of the practical ethical issues raised by the HBP and its goals are related to those of more general philosophical significance – concepts such as simulation, consciousness, human nature and identity, and problems in philosophy of mind, epistemology, and moral philosophy. WP12.2’s scholarship centres on these theoretical issues. It is crucial to unveil them, both to fully capture the ethical and social implications of the HBP, and to properly address and manage them in the future. This research provides not only a conceptual analysis of implications of having a unified knowledge of the brain, but also a conceptual analysis of human brain simulation in the HBP, its limits, aspirations and implications for our understanding of consciousness and the human mind. The work involves close collaboration with SP3 Cognitive Architectures, SP4 Theoretical Neuroscience, SP6 Brain Simulation, and SP10 Neurorobotics. It includes bilateral discussions between members of WP12.2 and SP members, and talks dedicated to the themes of the WP made by SP representatives at public conferences. The WP is divided into two tasks that are closely connected: T12.2.1 Simulation and Multi-Scale Theory of the Human Brain, and T12.2.2 Brain-Mind Relationships.

In February 2014 (M6), WP12.2 and WP12.6 held the first SP12 conference, titled: “How can neurotechnology – notably brain simulation as developed in the HBP – help assess, understand and access consciousness”. The invited speakers were Steven LAUREYS and Jacobo SITT. The second SP12 conference in June 2014 (M9), also jointly organised by WP12.2 and WP12.6, centred on the epistemology of simulation, and included talks by Hervé LE TREUT, Henry MARKRAM and Julie JEBEILE. Both conferences played a key role in clarifying the group’s work on brain simulation, and its impact on consciousness and identity. Finally, in collaboration with the Neuroethics Program at the *Centro de Investigaciones Filosóficas (CIF)* and *Universidad Torcuato Di Tella*, WP12.2 organised the neuroethics symposium: “*Cuestiones éticas y sociales planteadas por el conocimiento del cerebro*”, in Buenos Aires, Argentina, December 2014.

4.1 Main Outcomes of the First Studies of Conceptual and Philosophical Issues

4.1.1 The Meaning of Simulation

Simulation is a powerful method in science and engineering. However, simulation is an umbrella term, and its meaning and goals differ among disciplines. Rapid advances in neuroscience and computing draw increasing attention to large-scale brain simulations. Therefore, we asked: what is the meaning of simulation, and what should the method expect to achieve? In their first article, Yadin DUDAI and Kathinka EVERS discussed the concept of simulation from an integrated scientific and philosophical vantage point, and pinpointed selected issues specific to brain simulation [1]. They proposed a comprehensive practical taxonomy of simulation, and placed the goals of computer brain simulation



within it. They also identified and described a set of challenges and boundary conditions for current attempts at brain simulation. For example:

- The scarcity of neurobiological data: contemporary knowledge of the brain is limited, and the collection of data for large-scale brain simulation is not trivial. When federating data from different labs, even small differences in methodology and conditions can have an impact in terms of neuronal state and activity. The invariants identified may mask important features.
- Epistemic opacity: is the Vico maxim, that we can only understand what we can build, applicable to computer simulations of complex systems? Do we understand what we are able to imitate, model, or reconstruct - and in what sense?
- Representational parsimony: much of our scientific progress and understanding stems from our cognitive ability to extract and generalise laws of nature. Representational parsimony, describing the universe in a minimal number of equations, is regarded as the ultimate understanding. However, should we expect a small set of laws to adequately describe a complex adaptive system like the brain?

Engaging in large-scale brain simulation is a question of knowledge-dependent timing, proper integration of multiple bottom-up and top-down approaches, and realistic expectations. This was done while interacting with a wide community of experimental and computational neuroscientists, engineers and modellers at multiple levels of analyses worldwide, inside and outside the HBP.

4.1.2 Brain Knowledge, Simulation and the Human Mind

WP12.2's second line of research focused on how simulation is connected to understanding the mind. In neuroscience, problem-orientated computer simulations of specific systems and functions of the brain are used extensively to test predictions, validate conclusions and models, and to guide hypothesis-driven experiments and new models at various levels of analysis. In addition, rapid advances in neuroscience and computing draw increasing levels of attention to large-scale brain simulations. Against this background, WP12.2 asks: "how far can brain simulation contribute to explaining the brain and the mind?" The analysis defines the first three goals of brain simulation:

- 1) Serve as part of the rapidly expanding, rich methodological and technological toolkit of modern neuroscience.
- 2) Serve as a device in the planning, development and testing of brain-inspired technologies, such as bionic devices and hominid robots.
- 3) Contribute to the understanding of the brain and the mind.

Three types of issues relate to the potential explanatory power of large-scale brain simulations. These are methodological and technical issues, conceptual and philosophical issues, and those that refer to the role of consciousness. We still know very little about the role of consciousness, and therefore consider it as an issue of "type unknown". Methodological and technical obstacles are likely to be reduced or even resolved as the field develops, but conceptual issues may stay with us irrespective of scientific advances. A major example is epistemic opacity, i.e. the cognitive inaccessibility of intermediate steps in a highly complex process or mechanism. This remains, irrespective of whether the process or mechanism can be simulated on a computer, or the phenomenological outcome can be predicted. This type of profound and long-lasting conceptual obstacle should be taken into account when managing expectations of an improved understanding of the brain and mind. These results were included in the SP12 MS219 first report on how far brain simulation can explain the mechanisms of the mind.

In this report, WP12.2 analysed the complexity of the human brain, and the difficulties in identifying and examining the biological, social and contextual underpinnings of mental functions that confound the study of the causes and pathophysiology of mental disorders. Large-scale computer simulations of



the human brain were recently proposed as a method to circumvent some of these difficulties. In the second article, GOLD & DUDAI discussed selected conceptual and pragmatic issues related to mental illness simulation, and to computer simulation in particular. The authors first addressed the merits and limitations of animal models and computer models in the study of human mental disorders. They highlighted the need to tailor the vehicle and method of simulation to the goal of the simulation, and suggested future directions for maximising the usefulness of mental illness simulation. They argued that at the current state of knowledge, the biological-phenomenological gap in understanding mental disorders significantly limits the ability to generate high-fidelity biological and computational models of mental illness. Simulation focusing on limited realistic objectives, such as mimicking distinct biological and phenomenological attributes of specific mental symptoms, may, however, serve as a useful tool in exploring mental disorders.

4.1.3 Brain Knowledge and Consciousness Disorders

Over the last few years, neurotechnological tools and methods have been developed to assess residual consciousness in patients with DOC. Notably, the identification of activated brain areas and the real-time observation of cerebral activity potentially allow for a new form of technology-based communication. This would be in the absence of observable external behaviour or speech, thus going beyond the behavioural manifestation of awareness. This kind of communication raises epistemological and metaphysical issues. WP12.2 has explored several of these in a series of articles [4], one co-authored with SP3, on how to understand the relationship between brain activity, the target of neuroimaging, and awareness [2]. In view of the compensatory nature of brain functioning, WP12.2 also explored what kind of consciousness DOC patients could retain. Finally, as these analyses develop, WP12.2 has begun exploring the how to assess the capacity of DOC patients to make an appropriate, informed decision.

WP12.2 has scrutinised the numerous ethical issues raised by the neurotechnological assessment of residual consciousness in DOC patients. These include how to assess residual capacity of self-determination; whether, and to what extent, a prospective “cerebral communication” may be valid for informed consent; and whether the prospect of direct communication with DOC patients via neurotechnology requires clinical management, and the role of legal guardians, to be revised.

The role of brain simulation in studies of consciousness, and in communication with patients, is still at the proof of concept stage. However, the theoretical possibility of its application, and empirical results thus far strongly urge continued reflection on its possible clinical use.

4.1.4 The Brain's Social Contexts

Whilst much brain activity is spontaneous and intrinsic, the brain is also outwards-oriented and fundamentally social. The human brain juxtaposes opposite tendencies; it is engaged in highly individualistic and self-projective actions, but it also mediates co-operative social relationships. In WP12.2's analyses of the role of contexts in brain simulation [6, 7] (Report due in M30), research has focused on the following domains.

4.1.4.1 Cultural Imprinting on Brain Architecture

The human brain is an evaluative organ with reward systems engaged in learning, memory, and higher evaluative tendencies. It is our innate species-specific neuronal identity which causes us to develop universal evaluative tendencies. These include self-interest, control-orientation, dissociation, selective sympathy, empathy, and xenophobia, some combinations of which can cause problems. As previously mentioned, our neuronal identity makes us social, but also individualistic and self-projective. However, synaptic epigenetic theories of cultural and social imprinting on our brain architecture suggest the possibility of culturally influencing these predispositions. In an analysis of epigenesis by selective stabilisation of synapses, we discussed the relationships between genotype and brain phenotype. These include the paradox of non-linear evolution between genome and brain



complexity, the selection of cultural circuits in the brain during development, and the genesis and epigenetic transmission of cultural imprints. WP12.2 analysed the combinatorial explosion of brain representations, and the channelling of behaviour through "epigenetic rules" and top-down control of decision-making. In neurobiological terms, these rules are viewed as acquired patterns of connections (scaffoldings), hypothetically stored in frontal cortex long-term memory, which frame the genesis of novel representations and regulate decision-making in a top-down manner. Against that background, WP12.2 has proposed being "epigenetically proactive" [5], and adapting our social structures in both the short and the long term, to benefit, influence and constructively interact with the ever-developing neuronal architecture of our brains.

4.1.4.2 Human Identity

It is commonly believed that brain research will have an impact on human identity. For example, new treatments such as deep brain stimulation, neural grafting, and prostheses as clinical and therapeutic tools for treating diseased regions of the brain could raise questions about personal identity. The concern is that neuroscientific advances might alter a person's cognition, moods and behaviour, thus changing who they are as an individual. Brain simulation would raise an additional identity-related issue: if consciousness were achieved via simulation, would that be human consciousness? Attempting to answer requires understanding what is meant by "human identity". Since talk of identity can refer both to generic considerations that humans are supposed to share, and to concerns about individuals' self-conceptions and identity, it is crucial to distinguish between two kinds of identity concerns: those related to human identity (identity of humans qua humans), and those related to personal identity (numerical and narrative).

During the Operational Phase, WP12.2 will focus on two tasks. First, the team will continue research on conceptual issues raised by a unified understanding of the brain. Special attention will be paid to the role of contexts and cultural imprinting on brain architectures, and to examining aspects of the mind, and its role in identity, consciousness and notions of the self. The second task will explore the philosophical and ethical challenges raised by rapid advances in neuroscience and computing, such as the modelling of cognitive processes in silica, which draw increasing attention to large-scale brain simulations. It will focus on consciousness, self and identity.

5 The Public, Dialogue and Engagement

5.1 Goals and Nature of the Activities

The goal of WP12.3 is to help the HBP create a constructive dialogue with public and private stakeholders and the general public. It aims to maintain an intense engagement with external points of view, identify emerging controversies and formulate recommendations for HBP research and research priorities.

WP12.3 is divided into three tasks, each corresponding to a different kind of public and level of dialogue. T12.3.1, HBP Online Deliberation, will invite large ($n \geq 100$) groups from the general public to identify and discuss their expectations, and the issues arising from HBP research. T12.3.2, European Citizens' Conventions, will gather communities of respondents and inform them about HBP scientific work, allowing them enough time to understand the Project and give appropriate recommendations. T12.3.3 will focus on a dialogue between HBP participants and outside experts and stakeholders.

In the first 18 months, WP12.3 developed a plan for the content and form of the stakeholder involvement activities to be carried out in the Ramp-Up Phase (part of Milestone MS221).

5.2 Main Outcomes of the First Public Dialogue and Engagement Activities



5.2.1 Online Consultations Programme

The topics and open questions for T12.3.1's first online consultation have been defined on the basis of the initial research done in WP12.1, WP12.4 and T12.3.3:

- 1) Psychiatric and mental diseases and disorders: how should they be defined? For example, what is the relation between psychiatric diseases and neurological disorders? What do we know of them? What type of knowledge do we lack the most?
- 2) Ways to cure psychiatric and mental diseases, and expectations of present and future science: How are they treated? How should they be treated? How could science help in curing psychiatric and mental diseases? What are the most promising scientific areas?
- 3) Data sharing (the topic of "big data" is introduced in a non-technical manner): what are the general perceptions of sharing personal data (e.g. people willingly sharing personal information on social networks, versus third parties collecting personal data without individuals knowing)? What are the purposes of data collection and use? What are the main benefits, costs and risks? What kinds of personal data (private life, religion, political opinions, health, etc.) are seen as most sensitive?
- 4) Data sharing in the biomedical field: what are the purposes of health data collection? What medical data would you agree to share, and with whom? On which conditions? What are the benefits and the risks of sharing medical data? What should remain anonymous, and what does "anonymous" mean? Who should be the "gate-keeper" (the patient, the doctor, an independent platform, or someone else)? What should the patients know about the use of their data (the specific research use of their data, only the research field, etc.)? The focus is on consent and informed consent.
- 5) SP8 data integration strategy plan: a quick introduction to general HBP goals and tools and to SP8's specific goals, and presentation of the data integration plan. Questions for understanding the programme will include: what is its goal? How will it work? Can you rephrase it? Is it an acceptable programme? What are the main benefits and risks? Examples of topics and issues to consider include: possible breaches of privacy, trust in hospitals and using data from hospitals (paid by public taxes) in databases for improving public health.
- 6) SP8 brain disease signature plan: a presentation of the concept of disease signature. Questions for understanding this programme will include: what is its goal? How will it work? Is it an acceptable programme? What are the main benefits and risks? Examples of topics and issues to consider include: what if the number of diseases increases because of the signature system? Does the Project increase or decrease self-identity security (the idea that a person is accepted with their set of abilities and that they should not be forced to accept a perception of themselves that they do not agree with)? Will doctors still be useful? Will patients require more access to, and control of, their data?

The online tools and the sample for the first online deliberation have been defined. However, the researchers responsible for this task (Jean-Pierre CHANGEUX and Benjamin SIMMENAUER) have been extensively involved in revising the approach to ethics governance, as required by the HBP Review (see Foreword). Therefore, they did not have enough time to launch the first debate as planned. The fieldwork nevertheless took place in M20 (Milestone 222 achieved with a two-month delay). The results of the first consultation will be described in a separate report that will be first presented to SP12, and then distributed to the whole HBP Consortium. The next consultations are planned for M22 (future neuroscience) and M28 (future ICT).

5.2.2 Stakeholders Forum Programme

An overview of the stakeholder forums organised by FT, and descriptions of its involvement in the HBP, can be found on the dedicated webpage [6]. The twofold webinar organised by FT on multi-level



data federation and data protection, and disease signatures and personalised medicine, taught SP8 researchers about the privacy issues at stake in their plans to build a multi-level data federation structure. Among other items, SP8 realised that there are substantial legal and ethical issues linked to the identity of the data controller, and possible connected responsibilities if the HBP is to be seen as co-controller. Furthermore, the topic of informed consent was introduced, and SP8 researchers realised they may need to take action to obtain informed consent, or may need to develop a procedure for dealing with differences in regulation between EU and non-EU countries. These issues are becoming more complicated with new EU regulations on data protection and privacy. Finally, the researchers were presented with cases of collaboration between patient organisations and researchers. This aimed to help avoid controversy, ensure collaboration and avoid false expectations. In addition, contact was made between SP8 and specific privacy researchers and representatives from patient organisations. In the second part of the webinar, external researchers presented issues and questions concerning the HBP's plans for re-classifying mental diseases. The discussion of personalised disease signatures emphasised issues such as the shifting limits of disease and normality, and challenges created by new classifications in implementation and treatment systems.

A seminar in Copenhagen on 8 and 9 October 2014, involving SP8 and other SP12 partners (Institut Pasteur [P27], KCL, De Montfort University (DMU - P11)), examined the issues from the webinar in depth. The discussion provided information for both the HBP newsletter and the HBP Foresight Lab's first Foresight report. Results from the seminar were also used in the HBP's response to the first Ethics Review.

The newsletter "Living up to Privacy and Informed Consent in the Human Brain Project" [7], published December 2014, made the following recommendations:

- Clarify responsibilities: who is responsible for data protection and security?
- Perform PIA.
- Follow good anonymisation practices, as laid out in EU Opinion 05/2014 on anonymisation techniques.
- Make sure subcontractors follow good anonymisation techniques. It would be even better to avoid subcontracting.
- Stamp data with the type of consent given.
- Develop a partnering Project on privacy concerns in the Core Project.
- Seek informed consent where possible.
- Improve transparency and trust by:
 - Engaging in collaboration and dialogue with patient associations and external experts.
 - Managing expectations by being realistic about the research process and outcomes to patients, medical professionals and the public.
 - Listen to concerns and adapt accordingly.

SP8 has decided to go ahead with the recommendation to implement a PIA, as stated in the HBP's first response to the Ethics Review.

The first stakeholder forum dedicated to the second topic of the Ramp-Up Phase, future neuroscience, took place on 7 January 2015. The webinar 'Dual Use and Neuroscience' brought SP9 researchers in contact with leading scientists on dual use issues to discuss ways in which HBP research could become controversial. The webinar was organised in response to discussion on dual use within the HBP and ELSA. The recordings from the webinar are publically available [8].



In all its activities, WP12.3 collaborated across SP12 (12.1, 12.4, 12.5 and ELSA have all either contributed and/or participated in our events), and within the HBP (SP8, SP9).

The following activities are planned for T12.3.3 and T12.3.2 during the rest of the Ramp-Up Phase:

- Webinar in collaboration with WP12.1 on “Simulation, Cognitive Architectures, Future Neuroscience and the Human Brain Project” on 22 April 2015, 14:00–16:00 CET.
- Two-day seminar in collaboration with SP12.4, SP4, and SP7 on “Cognitive Architectures, High Performance Computing, Future Neuroscience and the Human Brain Project” at the European Institute for Theoretical Neuroscience (EITN) in Paris, on 21–22 May 2015
- Newsletter on the policy options emerging from the WP’s engagement activities to do with future neuroscience.
- One-hour discussion session on “Privacy and the Multi-level Data Federation Approach of the HBP”, and a poster exhibition presenting the HBP and privacy issues, at the three-day People’s meeting on the island of Bornholm, Denmark, 11–14 June 2015.
- Webinar on “Future ICT and Robotics” in September 2015.
- Two-day seminar on topics within “Future ICT and Robotics”.
- Newsletter on the policy options emerging from the WP’s engagement activities concerning “Future ICT and Robotics”.
- The EU citizen convention, from January–March 2016.
- A newsletter on the policy options emerging from the WP’s engagement activities with the public at the EU citizen conventions.

6 Researcher Awareness

6.1 Goals and Nature of the Activities

The aim of this WP is to foster ethical and social reflection within the HBP Consortium, and in particular among young researchers, clinicians and technology developers. T12.4.1 explores the ethical and social perceptions of HBP scientists, and began with a survey of the ethical and social views of HBP researchers, and their perceptions of responsible research and innovation in their areas of expertise. The survey will be followed by specific research in areas of concern, using interviews and focus groups. In addition, T12.4.1 will organise a series of half-day workshops on major HBP sites, each driven by members of the T12.4.1 team. The workshops will be open to all researchers at the site, and to other HBP researchers from surrounding areas. In the workshops, young researchers will be encouraged to present and debate their own analyses of the ethical and social implications of their work. They will also be encouraged to challenge their views with perspectives both from other groups, and from outside the Project.

After obtaining Human Research Ethics permission from DMU, and confirmation from WP12.5, nineteen directors and five senior staff members were identified as candidates for interview. After invitations and reminders, 20/24 (83%) directors and senior staff members were interviewed (15/19 [79%] directors and all senior staff). Interviews were conducted via telephone or Skype between December 2013 and June 2014, and lasted between 25 and 60 minutes. All interviews were transcribed in full and independently validated to ensure accurate representation of the audio recording. Analysis of 17/20 (85%) interviews from staff covering all work-packages was completed in August 2014, and after consultation and review, a final version was presented during the EU Review in M16.



After obtaining Human Research Ethics permission from DMU and confirmation from WP12.5, data concerning members of SP lists and general e-mail lists were downloaded from EMDesk, and manually analysed. Although this determined who was known to the HBP, there were many people working on the Project who had not been recorded in EMDesk. A survey of participants was therefore initiated via SP13 management contacts. The survey began in M14, two months after the intended start date, and was sent to SP list members. The survey population was completed in February 2015, and further invitations were sent. The overall population was 714 people, and so far 263 (37%) have responded. In M18, a substantial number responded following a reminder. Therefore, in-depth analysis will commence in M19.

6.2 Main Outcomes of the First Researcher Awareness Activities

6.2.1 Findings of the Interviews with SP Leaders

The main outcome of the interviews with SP Leaders is a list of ethical themes, i.e. issues that raised questions about the duties, roles, or moral, legal or professional status of stakeholders in the HBP.

6.2.1.1 Governance of Data and Platforms

In addition to data on animal and human brains, the HBP will gather data for the development of disease signatures, as part of Future Medicine, to create simulations. This large-scale task is needed for the successful use of data mining, and requires data on patients with neurological or psychiatric diseases from between 10 and 100 hospitals. The plan was to collect the information without obtaining individual consent in all cases. It was recognised that patient privacy should not be compromised, but that this may be necessary when the purpose was to improve public health. Proposals were made to keep identified data in the source institution, but this approach was seen as creating a trade-off between privacy protection and achieving scientific goals. The amount of data required may mean that the possibilities offered by seeking the consent of all patients were not fully considered. During the WP12.3 Danish Board of Technology Webinar of on 7 May 2014, it was found that patients were likely to adopt an altruistic and unexpectedly helpful position to the use of their data for neuroscience research.

Encouraging neuroscientists to disclose their experimental data to a repository before journal publication represents a change of practice for this community, and would require a relationship of trust with the HBP. This brings into question the desirability of a requirement to publish to the platform as a condition of research funding. Interviewees suggested that neuroscientists may not deposit their results into the various data sharing platforms, or that it would be of low quality. It was proposed that the HBP should develop a means of giving credit for all data published via this route, and to submit all data to scrutiny.

6.2.1.2 Responsible Research Practice

Interviewees were aware of the controversy surrounding non-human experimentation, but considered compliance with local ethical standards adequate. They often actively resisted further ‘policing’ by the ELSA, the REC, and WP12.5. It was also realised that policies for cross-culture or cross-national operation should be considered strategically. They require open communication with sponsors and the public that focuses on explaining the experiments and their purpose. The notion of common standards applies not only to animal experimentation, but also to personal data privacy and decisions about when to accept data. Another controversial aspect is the attempt to reduce animal experimentation; this would deny access to an important source of theory validation, and risks transferring the problem to simulated animals or humans.

The size of the Consortium, and the diverse backgrounds of its members, suggest that responsible research conduct should be carefully defined. This is especially important, as there will be a variety of scientific approaches within the Consortium and in future partner projects. Interviewees frequently



raised the issue of scientific integrity, and the fact that one of the contributions of the data-driven simulation would be to test the accuracy of data. This raises many questions, including that of how discrepancies between experimental data and the data-driven simulation should be investigated.

6.2.1.3 Development of Collaboration

The diverse membership of the Consortium and possible partner projects means that the ability to work together cannot be assumed. The structure of the HBP during the Ramp-Up Phase reflected the many approaches to neuroscientific research. Interviewees recognised that this scientific diversity should be embraced, and forums provided for the opportunity to discuss the broader scientific issues.

Several interviewees argued that, due to the enormity of the task, there may be insufficient funding to gather the necessary data from the brain. This raises the question of balance. Are participating laboratories mainly tasked with completing the necessary data collection? Or is their task to facilitate the development of the ICT Platforms and future collaboration? The conflict is the same for neuroscience researchers outside the HBP. What incentives are there to collaborate with the Consortium? The development of trust is two-way, and applications resulting from the work of the HBP will need to ensure that intellectual property is handled appropriately, especially if used by researchers outside the Consortium.

6.2.1.4 Foresight

Foresight is borrowed from responsible innovation. Here, it examines the possible implications of applying HBP research to ensure the most appropriate outcome for society. During the interviews, Future Medicine and autonomous decision making machines were considered.

Respondents were made aware of the effects a disease signature-based classification of people with neurological or psychiatric disease might have, through questions on this new ontology and epistemology. Many potential consequences for diagnosis, treatment and prevention, and for the rehabilitation of patients were highlighted during the WP12.3 webinar on 7 May 2014, where it was pointed out that the diagnosis of many psychiatric diseases can affect the patient beyond just the immediate symptoms.

Another frequently expressed idea was that a conscious computer is too far into the future to require consideration. However, one of neuromorphic computing's goals is to reduce power consumption enough to create portable devices. These could be autonomous decision-making systems that learn faster than humans. Coupled with the idea of cognitive chips, and robots able to perform technical functions around the home, in manufacturing, or as prosthetic limbs, this leads to questions of how such devices should be governed.

6.2.1.5 Maintaining Support

Respondents frequently pointed out that research is, by its nature, unpredictable, and that there was a disconnect between how the Project is planned and monitored. This is shown in particular in the use of performance indicators, which may stifle making necessary changes in response to new circumstances. This was seen to affect the management's ability to maintain support within the Project.

Concern was expressed over the Project's ability to collaborate with those outside the Consortium, and it was stated that the Project may be misunderstood as a clone of the Blue Brain Project. To move forward, it was proposed that the Project actively seek collaboration through joint conferences, which would give the Consortium the opportunity to integrate feedback from outside.

The interviewees recognised that claims made by the HBP have excited the public and raised expectations. Although it was recognised that the brain is at the very heart of a person's being, interviewees frequently proposed that the idea of a conscious computer was so far off as to not yet be worth considering. The preference was for a communications strategy that sought mainly to allay any fears that might arise from a conscious computer through education about the research.



The interviewees identified the possibility of abusing the platforms or applications. They suggested that there was a need for a public dialogue to allow people to call a halt to research, until they are ready for the consequences. This is seen as requiring an extensive programme of interaction, mainly through processes building on the aforementioned public education.

6.2.1.6 Responsible Research and Innovation

Most respondents found it difficult to answer the question of how HBP research and innovation could be conducted responsibly. However, the respondents touched upon all aspects of responsible innovation, from the anticipate, reflect, engage and act (AREA) framework, to the European Union's Horizon 2020 programme "science with and for society".

Many interviewees found the concept of anticipating the future effects of their research was problematic; while they understood that risk analysis was required, few were willing to undertake the process formally. Although rarely mentioned by name, the concept of reflection appeared in the need for scientific integrity; respondents often used the words "openness", "honesty" and "transparency". It was not often recognised that it was necessary to consider the societal consequences of their research.

6.2.2 The Role of the Ethics and Society Subproject

A striking feature of the interviews was the consistency with which respondents embraced working with SP12, but at the same time suggested that annual catch-up sessions would be adequate.

All of the social and ethical themes represent issues that will change as research progresses. They will require identification, assessment and action throughout the lifetime of the Project. A culture of openness and transparency will help uncover social and ethical issues. Frequent engagement between members of SP12 and the rest of the Consortium will help assess issues, and provide management with recommendations as to the best course of action. This close co-operation is something that should be championed by management. The following major ethical themes have been discussed, and were translated into questions in the survey.

- Data protection and individual privacy
- Governance of data provided to the shared platforms
- Prevention of abuse of shared platforms
- The appropriate use of animal experimentation and development of common standards
- Research integrity, including the maintenance of scientific diversity through collaboration
- Intellectual property
- The appropriate use of medical and robotic applications
- Communication with the wider neuroscience community
- Communication with the public and other stakeholders.

These should take place in collaboration with the rest of the HBP.

In the survey of all HBP staff, relating to the planned next steps, it is of particular relevance that 56/263 (21%) respondents have indicated they are willing to join SP12 in activities aimed at improving the understanding of social and ethical concerns that result from HBP work.

WP12.4 is tasked with communicating across the HBP. Interviews were held with all SP Leaders, and the online survey was sent to all HBP members, with responses from almost 50% of Subproject research staff. Preliminary reports from the interviews were presented to SP12 workshops during M5 and M8. Discussion of the content was related to the activities of WP12.1 The Foresight Lab, in regard to their report on Future Medicine, and to WP12.3 Public Dialogue and Engagement regarding



neuroscience. The report was also presented to the Ethics Reviewers during the EU Review. The survey of all HBP staff will show the importance staff place on the ethical themes identified during the interviews with Leaders, and may be a rich source of new ethical themes to consider.

In M21, WP12.4 aims to conduct a workshop with contacts identified via the interviews and the survey. This will raise awareness of ethical and social issues within other Subprojects and identify contacts with other SPs, thereby developing a continuous dialogue with other Subprojects, as suggested by the EC.

Any non-duplicate ethical issues identified by the survey and interviews will be fed into the ethical management structure that is being created in accordance with the requirements of the EU Review.

The future activities of WP12.4 will be geared towards meeting the requirements of the description of work and the EC's Ethical Review. Next, during the Ramp-Up Phase, workshops will be conducted with the ethics rapporteurs. These will provide an environment in which to examine scientific, social and ethical issues, thereby establishing links between the ethics management process and the rest of the HBP.

7 Governance and Regulation Activities

7.1 Goals and Nature of the Activities

The primary objectives of WP12.5 are to support HBP decision-making regarding issues with significant social and ethical implications, to help ensure that the Project fully complies with European and national legal and regulatory requirements, and to participate in European discourse on such issues.

WP12.5 coordinates HBP's participation in Ethical Reviews established by the European Commission (EC), including communication with the EC Project Officer, and manages supportive and administrative operations for the ethics committees, the ELSA and the REC. The ethics committees advise management on short- and long-range strategic planning and issues of policy, maintain a swift response to unexpected ethical, legal and social issues that may arise during the lifetime of the Project, and are aware of those that may exist in the future. They also advise on procedural and practical ethics in current and planned projects. This includes ensuring that all EU projects have appropriate IRB approvals which testify current compliance (during Project operations), and that non-EU projects are vetted (as an EU Ethics Review would demonstrate, e.g. ethics tables, etc.).

The Secretariat, engaging in both T12.5.1 and T12.5.2, and the two ethics committees, support HBP decision-making regarding significant social and ethical issues by communicating results of committee deliberations. To ensure that the Project fully complies with European and national legal and regulatory requirements, the Secretariat maintains, updates and performs quality checks on a data registry for all IRB approvals, and distributes these to EC reviewers in table form. The REC vets all non-EU research according to EU standards.

To participate in European discourse on such issues, the members of WP12.5 and the ethics committees may make oral or media presentations to major European ethics and social sciences bodies. These would be on topics concerning ethics, legal and social aspects in HBP research and its implications. They may also publish evidentiary and opinion papers, and attend international conferences, workshops and symposia.

The HBP's participation in EC-established Ethical Reviews, including communication with the EC Project Officer, is coordinated by: uploading materials to the EC provider site, responding to the EC Project Officer's requests, communicating with SP12 directors and ethics management, and maintaining communication on Ethics Reviews with the SP12 and HBP Communications managers,



including Deliverables, Disseminations, meetings (minutes, agenda etc.), and supplementary materials (slides etc.).

The WP12.5 Secretariat supports the ethics committees by providing for event planning and arrangements, including facilities, lodging, food and travel. WP12.5 also assists in recruiting and appointing members, and all necessary accompanying communication. Generally, it assists in communication with the Board of Directors, SP12, Ethics Rapporteurs (ERs), PORE (the point of registration of possible ethics, legal, philosophical and social issues) petitioners, the HBP Communications department, and HBP management. This includes, for example, editing and refining meeting minutes, and publishing them in EMDESK, the Collaboration Portal, and distributing them. It also creates and maintains individual profiles for the Collaboration Portal, the public and private websites relating to ELSA and REC, updates document registries, and facilitates portal communications among members and others. WP12.5 creates and maintains the PORE, and communicates what items exist (in name, and brief description and other key points) to SP12, REC, ELSA and the EC Project Officer.

7.2 Main Outcomes of the First Governance and Regulation Activities

In the first 18 months, ELSA has had three semi-annual meetings, and REC had five quarterly meetings. During M13-M18, REC and ELSA chairs and vice chairs participated in SP12 meetings, in HBP practice for the Ethics Review, and then participated in the Review itself.

The HBP Summit in Heidelberg was a lesson for both committees. For ELSA, it presented little opportunity for its members to enter the ethical discourse, since the members were meeting for only the second time. At the same time, REC had a heavy workload from animal and human research IRB approvals, and had yet to engage itself in the examination of the non-IRB tasks, e.g. robotics and Dual Use. WP12.5 directed itself primarily to collecting the information needed to ensure procedural ethics were enforced.

Members of ELSA, REC and the Secretariat participated in various activities:

- The WP12.1 and WP12.3 workshop in Copenhagen on 8 and 9 October 2014, joined by SP8, other SP12 partners, and representatives of ethics bodies in Europe, e.g. EUREC. This was followed by a newsletter, “Living up to Privacy and Informed Consent in the Human Brain Project”, published December 2014 [7].
- A webinar on “Dual Use and Neuroscience”, 7 January 2015 [8].
- The HBP rehearsal for the EC First HBP Ethics Review, in Frankfurt, 14 January 2015, and the second rehearsal in Brussels, 24 January 2015
- Joining each SP interview by the ethics expert reviewers at the EC First HBP Ethics Review in Brussels, 26-27 January 2015.
- ELSA and REC chairs and vice chairs held teleconferences every three to four weeks to prepare new proposals, address ethics issues and prepare for upcoming meetings.
- ELSA and REC members collaborated on an article that has been submitted to the American Journal of Bioethics.
- The PORE is taking petitions.
- Some ERs have been named, and have accepted their role as rapporteurs who can join bidirectional communication about ethics issues in their SP.



- The Ombuds program has been recommended, first by WP12.5, REC and ELSA, and later by the EC Ethics Reviewers. The program proposal needs to be prepared and reviewed by ethics management.
- A member of WP12.5 and a member of ELSA participated in a panel discussion on the HBP ethics program in Rome, 17 November 2014.
- Kevin Grimes gave a talk on the HBP ethics programme to the NEC and the EGE, in Rome on 19 November 2014.
- Kevin Grimes gave a talk on the HBP ethics programme to the EURECnet, with a presentation by SP8, in Maastricht, on 10 March 2015.
- ELSA Members presented a paper, “Strangers in Neuroscientific Research: On the Role of Social Scientists and Ethicists as Advisors in Ethical, Legal and Social Aspects of the Human Brain Project”, Institute of Zurich, Institute of Biomedical Ethics, Mainz, Germany, on 30 March 2015.

The data registry was adequate for collecting documentation attesting IRB approval when the projects involved animal or human research. However, the collection of materials to help the ethics committees understand the nature of ethical issues in areas outside the traditional IRB scheme was not adequate. For instance, non-EU research could not rest on the local IRB, and WP12.5 would have to provide a mechanism to help the committees establish the ethical propriety of those Project proposals.

The two committees displayed different trajectories; ELSA was less concretely engaged than REC, and REC wanted to share the core competencies of ELSA. The criticisms were followed by recommendations for a merger, which the committees agreed in Geneva on 26 March 2015. The committees proposed 13-15 members to form a new committee, the Ethics Advisory Council, which would meet three times yearly.

8 References

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- [9] Rose, N., “The Human Brain Project: social and ethical challenges”. *Neuron* **82**(6), 1212–1215 (2014).

Annex A: First Conference Papers

- Rose, N. “The Human Brain Project: social and ethical challenges”. *Neuron* **82**(6), 1212–1215 (2014). [9]

The paper discusses some social and ethical challenges raised by programs of research such as the HBP. These include the possibility of a unified knowledge of “the brain”, balancing privacy and the public good, dilemmas of “Dual Use”, brain-computer interfaces, and “responsible research and innovation” in the governance of emerging technologies.

- Dudai Y., Evers K., “To simulate or not to simulate: What are the questions?” *Neuron* **84**, 254–261 (2014). [1]

This article discusses the concept of simulation from an integrated scientific and philosophical vantage point and pinpoints selected issues that are specific to brain simulation.

- 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* (2014). doi: 10.1007/7854_2014_338 [3]

This paper starts by analysing recent advances in the neurotechnological assessment of residual consciousness in patients with DOC, and in neurotechnology-mediated communication with them. Ethical issues arising from these developments are described, with a particular focus on informed consent. Against this background, we argue the need for further scientific efforts and ethical reflection in the neurotechnological assessment of consciousness and “cerebral communication” with verbally non-communicative patients.

- Evers, K., “Can we be epigenetically proactive?”. In T. Metzinger & J. M. Windt (Eds.) *Open MIND*. (Frankfurt am Main: MIND Group 2015). [5]

In an analysis of epigenesis by the selective stabilisation of synapses, this article discusses the relationships between genotype and brain phenotype, including the paradox of non-linear evolution between genome and brain complexity, the selection of cultural circuits in the brain during development, and the genesis and epigenetic transmission of cultural imprints. It discusses the combinatorial explosion of brain representations, the channelling of behaviour through epigenetic rules, and the top-down control of decision-making. In neurobiological terms, these “rules” are viewed as acquired patterns of connections (scaffoldings), hypothetically stored in frontal cortex long-term memory, which frame the genesis of novel representations and regulate decision-making in a top-down manner. Against that background, the article proposes being epigenetically proactive, and adapting our social structures in both the short and the long-term, to benefit, influence and constructively interact with the ever-developing neuronal architecture of our brains.