Human Brain Project

Co-funded by the European Commission

Project Number:	284941	Project Title:	Human Brain Project

Document Title:	Ethics and Society Research Plan
Document Filename:	HBP_SP12_140425_D12.6.1_ResearchPlan_RESUBMITTED_FINAL.docx
Deliverable Number:	D12.6.1
Deliverable Type:	PU
Work Package(s):	WP 12.6
Planned Delivery Date:	M 6 / 31 March 2014 (To be resubmitted M21 / 30 June 2015)
Actual Delivery Date:	M 7 / 25 April 2014 (Resubmitted 7 July 2015)

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Abstract:	This Ethics and Society Research Plan is the first Deliverable -D12.6.1- from SP12. It establishes a precise roadmap for each of the tasks included in the HBP Ethics and Society programme.
Keywords:	Ethics, Society, Responsible Innovation, Foresight, Philosophy, Public Dialogue, Engagement, Stakeholders, Awareness, Governance, Regulation, Ethics Committees, EAB.

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Executive Summary

The goal of SP12's Ethics and Society Programme is to help the Human Brain Project (HBP) identify the numerous social, ethical and philosophical implications of its research, and address them in an open and transparent manner. The Ethics and Society Programme is composed of six different Work Packages (WPs) with closely integrated roadmaps. The first WP on Foresight Research evaluates the potential industrial, economic and social consequences for Europe of the new knowledge and technologies produced by the HBP. The second WP on Conceptual and Philosophical Research provides a conceptual analysis of human brain simulation in the HBP and its implications for our understanding of the mind and consciousness. The third WP on Public Dialogue and Engagement helps the HBP create a constructive dialogue with public and private stakeholders and with the general public. The fourth WP on Researcher Awareness fosters ethical and social reflection within the HBP Consortium by exploring perceptions of ethics, the role of the project in society, and responsible innovation. The fifth WP on Governance and Regulation facilitates HBP decision-making on issues with significant social and/or ethical implications, and supports the establishment and operation of HBP's Ethics, Legal and Social Aspects Committee (ELSA) and Research Ethics Committee (REC). The sixth WP provides scientific coordination for the whole Ethics and Society Programme.

1. Introduction

1.1 Objectives

This Ethics and Society Research Plan is SP12's first Deliverable, D12.6.1. The Plan establishes a roadmap for each of the tasks included in the HBP Ethics and Society Programme. During the HBP ramp-up phase, the Plan will serve as the reference document for the SP12 committee and HBP general management to measure the development of the Ethics and Society research programme.

Paragraph 1.2 describes the mission of the Ethics and Society Programme, which is to implement a strategy of responsible innovation. Paragraph 1.3 describes the way the programme coordinates the activities of the different work packages and tasks involved in research and public dialogue activities. Paragraph 1.4 provides a high level description of the indicators used for monitoring progress.

Sections 2 to 7 describe the work plans for each SP12 work package, including their respective Tasks. We introduce each Task's objectives, methods, resources, and provide detailed progress and performance indicators.

1.2 HBP and Responsible Innovation

HBP research and technology development has numerous short-term and long-term social, ethical and philosophical implications. The project has a commitment to identify these concerns early and to address them transparently. In particular, early engagement will provide scientists with opportunities to understand public reaction to their work and its implications, and to hone their research objectives and processes in the light of these reactions.

1.3 Ethics and Society Programme Roadmap

The Ethics and Society Programme will draw upon methods developed during empirical investigations of emerging technologies in genomics, neuroscience, synthetic biology, nanotechnology and information and communication technologies. It will also use methods based on the biomedical tradition of engaging ethical issues through the application of formal principles – now usually implemented through ethical review processes.

The Ethics and Society Programme has five main goals for the ramp-up phase.

1) Establish and support two independent, management-level committees to provide ethical governance within the project.
    1. An Ethical, Legal and Social Aspects Committee (ELSA; WP12.5.1) to monitor and provide guidance on the project's long-term ethical and social implications
    2. A Research Ethics Committee (REC; WP12.5.2) to manage and provide advice on issues related to practical and procedural research ethics (studies using human volunteers, animal research, use of clinical data collected for other purposes, applications to ethics committees etc.)
2) Set up and start operating the Foresight Lab, which will be responsible for monitoring HBP research and investigating its social and ethical implications for European citizens,

industry, economy and society. The lab should be fully operational by the end of Month 9 (WP12.1).

3) Investigate conceptual and philosophical implications of brain simulation and the emergence of new insights into the relationship between brain and mind. We will publish the first results before the end of the Ramp-up Phase (WP12.2).

4) Launch the HBP online deliberation, a European Citizens' Convention and a stakeholders' forum – all part of the HBP's broader programme of public dialogue and engagement (WP12.3).

5) Launch a survey of ethical perceptions among HBP researchers. This will form the basis for a broader programme of researcher awareness during the operational phase (WP12.4).

1.3.1 Integration of SP12 Research and Public Dialogue Activities

In addition to the individual plans for the work packages described below, WP12.1 (Foresight), WP12.2 (Conceptual and philosophical issues), WP12.3 (Public Dialogue) and WP12.4 (Researcher Awareness) will coordinate their activities and align their research programs as much as possible to facilitate work based on the participation of stakeholders, citizens and HBP researchers.

The strategy is to follow the work plan of WP12.1, which is structured into three thematic cycles corresponding to its planning of deliverables (D12.1.1-3):

1) Month 4 to Month 18: HBP impacts on future medicine

2) Month 10 to Month 24: HBP impacts on future neuroscience

3) Month 16 to Month 30: HBP impacts on future information and communications technology (ICT) and robotics

We have thoroughly defined the research plan for the first cycle on future medicine (Cycle 1). If all partners consider the following protocol satisfactory, we will organise the next two cycles similarly.

Tasks	Action	Date (Month)
T12.4.1	Interviews with SP leaders, to generate a list of ethical and societal issues.	M4-M5 (completed)
T12.1.1	Desk research on issues raised by big data in medical context (privacy, informed consent, etc.), including review of regulations and media.	M4-M5 (completed)
T12.2.2 and T12.6.1	First SP12 conference on consciousness in clinical contexts and on brain simulation as a method for assessing consciousness. The presentations and discussions will feed the desk research and preparation of Foresight reports in WP12.1, and the list of ethical issues as well as the preparation of the online survey in WP12.4.	M5 (completed)
T12.1.1 and T12.3.3	Joint webinar with SP8 researchers and non-HBP scientists and/or stakeholders in the domain of future medicine.	M7
T12.1.1 and T12.3.3	One-day seminar with non-HBP stakeholders and SP8 researchers in the domain of future medicine.	M9
T12.2.2 and T12.6.1	Second SP12 conference on brain simulation and its expected impacts on the future of medicine. The presentations and discussions will feed the desk research and preparation of Foresight reports in WP12.1, and the list of ethical issues as well as the preparation of the online survey in WP12.4.	M9
T12.1.1	Writing of a scenario planning (potential HBP impact on future medicine) draft report in T12.1.1. T12.3.1 uses it as an input for the development of survey materials in the online deliberation in M11. T12.3.3 uses it as an input for the recommendation workshop in M11.	M9 to M12
T12.3.3	Workshop for concrete recommendations for actions in the HBP (big data, privacy issues). Possible interest groups: patient groups, regulators, medical people, data protection groups. All of this will feed into the upcoming online deliberation in T12.3.1 and the researcher survey in T12.4.1.	M11
T12.3.1	First online deliberation is running. Results will be integrated into the foresight study and will serve as an input in the researcher survey in T12.4.1.	M12

T12.2.2 and T12.6.1	Third SP12 conference on brain diseases. The presentations and discussions will feed the desk research and preparation of Foresight reports in WP12.1.	M12

Table 1: Integration of SP12 Research and Public Dialogue Activities

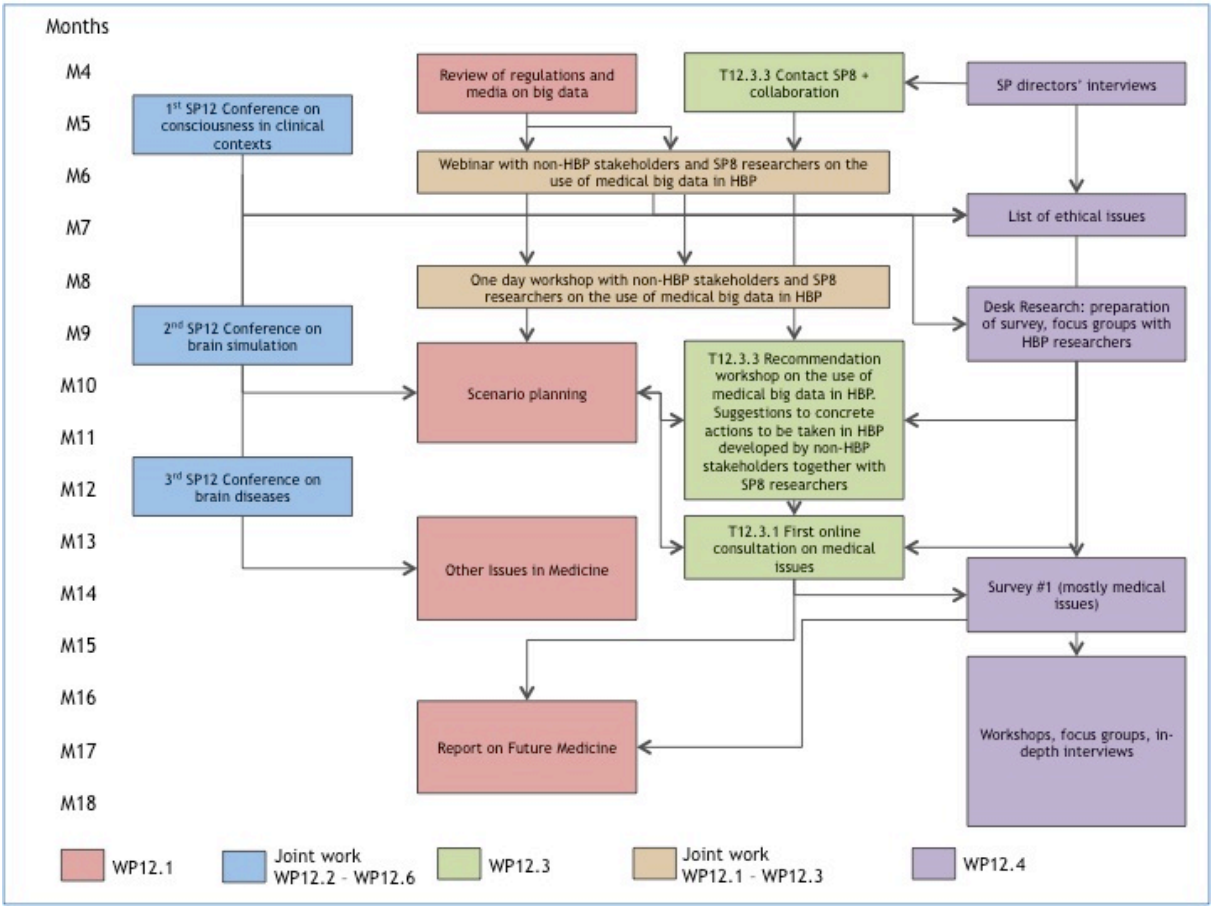

Figure 1: Summary of the 1st cycle integration plan

1.4 Measuring Performance and Progress in SP12

SP12 involves research (WP12.1, WP12.2), public dialogue (WP12.3), a survey of ethical awareness within the HBP Consortium (WP12.4), and the organisation of governance activities (WP12.5). We will assess progress using three types of metrics: categorical stage indicators, numerical indicators, and quality indicators.

Targets for categorical stage indicators will specify the stage an activity should reach by a given point in time. Numerical indicators will be used to assess the progress and performance (e.g. visibility) of SP12 activities. Quality indicators will be used to judge reports and technical deliverables by describing qualitative properties that cannot be evaluated using a numerical indicator. Quality indicators are based on methods used by journals to evaluate papers or by funding agencies to evaluate funding requests.

To evaluate an SP12 activity, the responsible actor (central management or SP work package scientific coordinator) will define the key dimensions of interest, a weight to be attributed to each dimension, a threshold value for acceptability on each dimension (optional), and a minimum threshold for the whole score. By default the dimensions will be science and technology quality (weight 0.4), relevance to the project (weight 0.4), and quality of writing (weight 0.2).

The subproject leader will distribute the draft deliverable to one or more internal or external reviewers who were not involved in the work. Each reviewer will attribute the activity a score between one and five for each of the previously specified dimensions. The scores given by reviewers will be used to calculate (i) a mean score for each dimension, and (ii) an overall score for the deliverable (the weighted sum of the scores for each dimension). The deliverable will be accepted if and only if the mean scores are on or above threshold for all dimensions and the overall score is above threshold.

Each indicator used to measure the progress and performance of a given SP12 activity is described at the end of the section devoted to its respective task or WP.

2. Foresight: Industrial, Economic and Social Consequences of the HBP (WP12.1)

The aim of WP12.1 (Nikolas Rose, King's College London) is to evaluate the potential industrial, economic and social consequences for Europe of the new knowledge and technologies produced by the HBP. The work, which is the responsibility of the HBP Foresight Lab (T12.1.1), is to conduct systematic foresight exercises to identify and evaluate these impacts along three themes, for each of which it will deliver a Foresight Report: 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).

2.1 The HBP Foresight Lab (T12.1.1)

2.1.1 Objectives

Task T12.1.1 (Nikolas Rose, King's College London) consists of setting up and running the HBP Foresight Lab. The objective of the HBP Foresight Lab is to produce and deliver three themed Foresight Reports: Foresight Report on Future Medicine in Month 18 (D12.1.1),

Foresight Report on Future Neuroscience in Month 24 (D 12.1.2) and Foresight Report on Future Computing/Robotics in Month 30 (D12.1.3). The foresight activities will identify new developments and evaluate their potential industrial economic and social impact over five, ten, and twenty-year horizons. They will also assess key ethical concerns such as privacy, autonomy, transparency, risks and benefits, responsibility, accountability, equity and justice.

We will disseminate Foresight Reports widely within the HBP and to public audiences, encouraging on-going reflection on the work of the project and the ethics of responsible research and innovation; increasing awareness of potential risks; helping to manage risks; and maximising the industrial, economic and social benefits of the project.

The Foresight Report on Future Medicine, to be delivered in Month 18 (D12.1.1), will focus on issues related to 'big data', data federation and integration, regulation, and the identification of disease signatures (personalisation). Within HBP, stakeholders consulted and involved in foresight activities will come from work packages in SP8 (Medical Informatics Platform) and WP11.2 (Applications: Future Medicine). We will engage other key stakeholders, notably bioethics councils, regulating and policymaking bodies, SP8 collaborating hospitals, civil liberties and data protection advocacy groups, pharmaceutical companies, and patient associations.

The Foresight Report on Future Neuroscience will be completed in Month 24 (D12.1.2). Key issues will be identified through a first phase of consultation followed by a second phase of foresight activities. These activities will involve stakeholders internal to the HBP (researchers in SPs1-6 and WP 11.1) as well as organizations and individuals external to the HBP. Notable external participants will include the European Institute for Theoretical Neuroscience to be established by SP4, funding agencies, professional associations, neuroscience research groups not involved in HBP, other large neuroscience projects and the lay public.

The Foresight Report on Future Computing/Robotics will be delivered in Month 30 (D12.1.3).). Key issues will be identified through a first phase of consultation followed by a second phase of foresight activities. These activities will involve stakeholders internal to the HBP (researchers in SPs 7, 9, 10 and WP11.3) as well as organisations and individuals from outside the project. External participants will include members of PRACE, representative ICT businesses such as SAP Research (T11.3.1), robotics research groups not involved in the HBP, funding agencies, professional associations and the lay public.

2.1.2 Methods

T12.2.1 will systematically consult with existing and potential stakeholders internal and external to the HBPs. We will conduct T12.1.1 stakeholders' consultation activities in coordination and *ad hoc* collaboration with T12.3.1, T12.3.2, T12.3.3 and T12.4.1.

Table 2: Implementation of T12.1.1

Task	Action	Date (Month)
T12.1.1	Recruit and appoint Research Officers and Project Officer by Month 3	M3 (completed)
T12.1.1	Review literature on Foresight and anticipatory governance, with a particular focus on evaluating the methods used in this work	M3 (completed)
T12.1.1	Review regulations on big data and medical data sharing in preparation for webinars and workshop co-organised under the lead of T 12.3.3	M6 (completed)
T12.1.1	Under the lead of T 12.3.3, co-organise up to 2 webinars with SP 8 researchers and other stakeholders in the domain of Future Medicine	M7
T12.1.1	Under the lead of T 12.3.3, co-organise a one-day seminar with SP 8 researchers and non-HBP relevant stakeholders' representatives and experts in the domain of Future Medicine	M9
T12.1.1	Under the lead of T 12.3.3, co-organise a solution-oriented task force meeting (1 or 2 days long) focussed on Future Medicine	M12
T12.1.1	On-going survey of HBP expectations, promises, fears, hopes and outcomes, mostly through the media monitoring provided in HBP Collaboration and through public dialogue activities led in T 12.3.1 and T 12.3.2	M4 to M30
T12.1.1	Undertake further Foresight work with special focus on future medicine	M11 to M16
T12.1.1	Hold a foresight activities workshop with key stakeholders to explore their perceptions of the contributions to be made by the HBP in the domain of Future Medicine	M11 to M16

Task	Action	Date (Month)
T12.1.1	Write first Foresight Report on Future Medicine	M17 to M18
T12.1.1	Hold a future scoping workshop with key stakeholders in the domain of Future Neuroscience	Between M19 and M22
T12.1.1	Write second Foresight Report on Future Neuroscience	M23 to M24
T12.1.1	Hold a future scoping workshop with key stakeholders in the domain of Future Computing and Robotics	Between M25 and M28
T12.1.1	Write third Foresight Report on Future Computing and Robotics	M29 to M30

2.1.3 Resources

The WP12.1 team is comprised of four researchers:

1. Prof. Nikolas Rose, Principal Investigator, Professor of Sociology and Head of the Department of Social Science, Health & Medicine (SSHM) at KCL. Prof. Rose's special expertise lies in the analysis of the social and ethical implications of developments in science, technology and the life sciences.
2. Dr. Claire Marris, Co-investigator, Senior Research Fellow, with special expertise on the nature, role and translational possibilities of advanced biosciences and biotechnology, and in particular understandings of science, risk and uncertainty among publics, scientists, and risk regulators.
3. Dr. Christine Aicardi, Research Associate, who specialises in socio-historical studies at the intersection of mind/brain sciences and computer science, in particular computational neuroscience and Artificial Intelligence.
4. Dr. Michael Reinsborough, Research Associate, who works on Technology Assessment: public engagement, alternative metrics for assessment, socio-technical integration, anticipatory governance, real time technology assessment, and new policy trajectories for ELSI work.
5. Paola Bello, EU Project Officer, who assists the PI and the research team in administering the project, producing reports for the EC and project's partners, and in organising varied knowledge transfer and dissemination activities.

2.1.4 Measuring performance and progress in T12.1.1

Task	Activity	Target (Month) 6	12	18	24	30
T12.1.1	1st foresight report (Future Medicine)	Preparation	Writing	Completed	Completed	Completed
T12.1.1	2nd Foresight report (Future Neuroscience)		Preparation	Writing	Completed	Completed
T12.1.1	3rd Foresight report (Future Computing/Robotics)			Preparation	Writing	Completed

Table 3: Progress on T12.1.1 reports (D12.1.1, D12.1.2, D12.1.3)

Task	Indicator	Target	Date (Month)
T12.1.1	Number of Citations of the Foresight Reports in HBP internal reports and publications	3	M30
T12.1.1	Number of scientific publications (papers accepted in conferences and high impact journals, books, reports) citing the Foresight Reports	1	M30
T12.1.1	Number of media articles citing reports from Foresight Lab	2	M30

Table 4: Numerical indicators for T12.1.1

3. Conceptual and Philosophical Issues (WP12.2)

The goal of WP12.2 (Kathinka Evers, Uppsala University) is to provide a conceptual analysis of human brain simulation in the HBP: its meaning, distinct theoretical approaches, underlying assumptions, and the implications for our understanding of the mind and consciousness.

3.1 The Concept of Human Brain Simulation (T12.2.1)

3.1.1 Objectives

T12.2.1 (Yadin Dudai, Weizmann Institute) will provide a conceptual analysis of what it means to simulate the human brain *in silico*, clarifying the conceptual assumptions and

implications of 'top-down' versus 'bottom up' approaches and examining how and to what extent these historically conflicting concepts can be reconciled, e.g. by conceiving them as providing complementary perspectives on the same underlying reality. The analysis will address how far human brain simulation is intended to simulate only basic capabilities of the brain, and how far it seeks to replicate its full cognitive capabilities (i.e. by achieving the ability to pass the Turing test. The analysis will also address the issue of whether a simulated brain will be adjustable to simulate not only type (i.e. a prototypical "average" brain) but also tokens, (i.e. individual brains), and if so, if whether this could enable the simulation of individuals.

A large body of data demonstrates that input from the body can critically influence the brain's metabolic states and internal somatosensory signalling, and it is well known that social input shapes the way the brain anticipates and reacts to the world that it is genetically predisposed to explore. A central theme will thus be the relationship between the brain's endogenous activity and external influences, and the extent to which simulation must reflect the brain's embodiment and social contexts.

3.1.2 Methods

T12.2.1 is an essentially cross-disciplinary task that will use knowledge from science, ICT and philosophy. The task will use conceptual analysis - a tool from the tradition of analytic philosophy – to break down scientific concepts (e.g. simulation) into their constituent parts, –thereby gaining a better understanding of the underlying philosophical issues.

3.1.3 Implementation

Task	Action	Date (Month)
T12.2.1	Preliminary research on the epistemology of simulation and the HBP notion of a brain simulation	M1 to M6 (completed)
T12.2.1	First draft of a joint paper by Kathinka Evers, Yadin Dudai and members of the SP6 on 'Brain simulation'	M6 (completed)
T12.2.1	Second SP12 conference (under the lead of T 12.6.1) on simulation on June 26-27th at Institut Pasteur in Paris, with SP6 members.	M9
T12.2.1	First report on how far brain simulation can explain mechanisms of the mind (M219).	M18

Table 6: Implementation of T12.2.1

3.1.4 Resources

The task involves the part-time work of task-leader Prof. Yadin Dudai (neuroscience), Prof. Kathinka Evers (philosophy of mind, philosophy of neuroscience, neuroethics) and Dr. Azgad Gold, MD (psychiatry) and PhD (Philosophy of Science), hired by Yadin Dudai as a

consultant at Weizmann Institute. Dr Gold is working on the meaning, boundary conditions and implications of simulation of mental disease.

WP12.2's analysis, conducted in continual contact with field scientists, will assist other subprojects in taking account of bodily and social input in setting and adjusting goals for simulation research. Most specifically, we will collaborate closely with SP6: Brain Simulation.

3.1.5 Measuring performance and progress in T12.2.1

Task	Indicator	Target	Date (Month)
T12.2.1	Number of Citations of the report on "the relationship between the brain, body and environment for brain simulation (M219)" in HBP internal reports and publications	3	M30
T12.2.1	Number of Papers accepted in conferences and high-impact journals (only papers directly referring to HBP research)	3	M30

Table 7: Numerical indicators for T12.2.1

		Target (Month)				
Task	**Activity**	6	12	18	24	30
T 12.2.1	Report on the relationship between the brain, body and environment for brain simulation	Preparation	Preparation	Preparation	Writing	Completed

Table 8: Progress on T12.2.1 report

3.2 Brain – Mind Relationships (T12.2.2)

3.2.1 Objectives

T12.2.2 (Kathinka Evers, Uppsala Universitet) will analyse the implications of brain simulation for concepts of mind and consciousness. In particular, the study will examine how brain simulation can shed light on our understanding of consciousness, and consciousness disorders; if a brain simulation could develop states and properties that are not present in the input to the simulation, and if so what this would mean for the simulation's cognitive or emotional abilities.

Many aspects of humans' ability to interact with their biological and social milieu depend on their capacity for "attribution": the ability to capture and internally simulate the internal processing and reactions of others. It has been suggested that a number of

disorders, including those within the autistic spectrum, may involve dysfunctions in these capabilities. T12.2.2 will ask how far HBP brain simulation can shed light on this capability. Can neurotechnological advances help us read other minds? Can a simulated brain reproduce the behavioural characteristics? Would such a brain be able to distinguish between the original and its simulacra, i.e. fellow simulated brains? The analysis of the different possible scenarios, which we will perform in close collaboration with other sub-projects, will contribute to studies of conscious and non-conscious subjective awareness in perception, emotion, and intentionality, and to investigations of non-human animal consciousness.

3.2.2 Methods

WP12.2 will use the same methods as WP12.1.

WP12.2's analysis of these questions will assist other subprojects in taking account of concepts of mind and consciousness when setting and adjusting goals for simulation research. Most specifically, we will perform the work in this task in close collaboration with SP3: Cognitive Architectures. The results will be disseminated throughout the HBP.

3.2.3 Implementation

Task	Action	Date (Month)
T12.2.2	Preliminary research	M1 to M6 (completed)
T12.2.2	First publication by Kathinka Evers and Mariano Sigman (SP3): Possibilities and limits of mind-reading: A neurophilosophical perspective, Consciousness and Cognition 22 (2013) 887–897 (Impact factor 2,31)	M6 (completed)
T12.2.2	First SP12 conference (under the lead of T 12.6.1) on neurotechnological assessments of consciousness, including ethical and societal aspects, Institut Pasteur, Paris on February 27-28th (completed). This meeting has involved members of the SP3 on 'Brain function and cognitive architectures'.	M5 (completed)
T12.2.2	Second publication by Michele Farisco, Kathinka Evers, Carlo Petrini, Biomedical research involving patients with disorders of consciousness: ethical and legal dimensions, Part I, (Note: the article is about The directive 2001/20/EU.) Accepted for publication in a special issue of the "Annali dell'Istituto Superiore di Sanità" (Completed, impact factor 0.76, registered in PubMed)	M6 (completed)
T12.2.2	Submission to a high impact science journal of a joint paper by Kathinka Evers and collaborator Michele Farisco on "Externalisation of Consciousness"	M6 (completed)
T12.2.2	Submission to a high impact science journal of a joint paper by Kathinka Evers and Jean-Pierre Changeux on "Can We Be Epigenetically Proactive?"	M6 (completed)
T12.2.1	Second SP12 conference (under the lead of T 12.6.1) on simulation on June 26-27th at Institut Pasteur in Paris, with SP6 members.	M9
T12.2.1	First report on the relationship between the brain, body and environment for brain simulation (M220)	M30

Table 9: Implementation of T12.2.2

3.2.4 Resources

The task involves the part-time work of task-leader Prof. Kathinka Evers (philosophy of mind, philosophy of neuroscience, neuroethics), Dr. Michele Farisco (philosophy of neuroscience, neuroethics), and Karl Sallin (philosophy of mind, language and mathematics). All participants in the task have long-standing experience in analyses of problems pertaining to consciousness and the human brain, communicated in a wide range of international publications.

3.2.5 Measuring performance and progress in T12.2.2

Task	Indicator	Target	Date (Month)
T12.2.2	Number of Citations of the report on "the relationship between the brain, body and environment for brain simulation (M219)" in HBP internal reports and publications	3	M30
T12.2.2	Number of papers accepted in conferences and high-impact journals (only papers directly referring to HBP research)	3	M30

Table 10: Numerical indicators for T12.2.2

		Target (Month)				
Task	Activity	6	12	18	24	30
T12.2.2	Report on brain simulation and mind-brain relationships (M220)	Preparation	Preparation	Preparation	Writing	Completed

Table 11: Progress on T12.2.2 report

4. The Public, Dialogue and Engagement (WP12.3)

The goal of WP12.3 (Jean-Pierre Changeux, Institut Pasteur) is to help the HBP create a constructive dialogue with public and private stakeholders and with the general public, maintaining an intense engagement with points of view external to the HBP, identifying emerging controversies, and formulating 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. While 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 expose them to information about HBP scientific work, allowing them

enough time to gain a deep understanding and express sensible recommendations. T12.3.3 will focus on a dialogue between HBP participants and outside experts and stakeholders.

4.1 HBP Online Deliberation (T12.3.1)

4.1.1 Objectives

The goals of T12.3.1 (Jean-Pierre Changeux, Institut Pasteur) are to:

1) Gather the general public's perception of the HBP, understanding of the scientific content, its meaning and purpose
2) Recognise the public expectations towards HBP's research and findings, the nature of the anticipated benefits, for private individuals and their personal satisfaction and wellbeing, and for individual citizens who participate in civic responsibilities as members of a democratic society
3) Obtain rapid but well-argued feedback from the general public on the ethical and social issues listed in WP12.1, WP12.2 and WP12.4. T12.3.1 will help us understand which of these issues are considered as important by the general public, ranking them according to the public perception of their significance, and explaining the reasons why the public is concerned about them.

T12.3.1 will inform the SP12 and the HBP management of the ethical and social priorities perceived by 'regular' European citizens, and suggest ways of addressing them to prevent potential misunderstandings or conflicts.

4.1.2 Methods

T12.3.1 will organise three online interactive consultations during the ramp-up phase, each involving a recruited sample of 100+ people in a single European country. Participants will use a dedicated online restricted access platform equipped with moderating facilities (tags, creation of polls, etc.) to debate ethical issues and dilemmas raised by HBP research, discoveries and technologies. Respondents to these deliberative surveys do not answer a rigid set of questions determined *a priori,* and are not interviewed individually: they are invited to share ideas, and to interact with the entire community. A team of moderators ensuring an active and substantial participation will facilitate the debate. The moderators will also identify 'leitmotivs' in the discussions and create 'micro polls' accordingly, allowing participants to vote on the ideas and opinions expressed in the course of the deliberation. This approach has the following advantages over more classical surveys:

- It delivers both qualitative and quantitative data
- It is more realistic than other approaches, reproducing the contextual process of opinion making on complex and uncertain issues (like the consequences of HBP)
- It helps monitor the influential opinions within a group and detect potential opinion trends
- Web-based tools provide an economic and ergonomic solution to organise dialogues with several dozens of people each time, and in different European countries

To prepare these online consultations, T12.3.1 will develop a specific set of multimedia (texts, pictures, videos, webpages, etc.) documents for each of them, to be introduced

during the debates. The content of these stimuli will be elaborated in collaboration with the other SP12 work packages, and, if needed, with the support of the relevant HBP sub-projects. The participants will thus be able to go beyond a superficial understanding of the HBP's activities and of their potential consequences.

Following the debates, we will analyse the content using quantitative and qualitative methods and summarise it in reports, which will then be made available to the HBP board and to the public.

4.1.3 Implementation

T12.3.1 will organise 3 online consultations during the ramp-up phase. Each of them will take place in a different European country (France, Germany and the UK) and last one week. Each will focus on a well-defined topic and will introduce specifically designed materials for public feedback, summarising important HBP research or plans.

Following the schedule for social and engagement activities defined in the chapter 8 of the present document, the first consultation (France) will deal with future medicine, specifically medical data federation and personalised medicine in the HBP context. The second will focus on future neuroscience and will take place in Month 22. The third, on future ICT and robotics, will take place in Month 29.

Task	Action	Date (Month)
T 12.3.1	Choice of a contractor (research institute) for the online platform and the recruitment of participants; subcontracting procedures.	M7
T 12.3.1	Definition of the topics for the first online consultation.	M3 to M9
T 12.3.1	First proposal of topics to be circulated among SP12 for reviewing and suggestions	M9
T 12.3.1	Final list of topics	M10
T 12.3.1	Development of the materials for the survey (in close collaboration with SP12 and HBP management)	M7 to M10
T 12.3.1	Recruitment of participants for the first consultation	M11
T 12.3.1	Fieldwork	M12
T 12.3.1	Analysis of the data, writing of the report	M12 to M13
T 12.3.1	Same process than above for the next two consultations	M12 to M30

Table 12: Implementation of T12.3.1

4.1.4 Resources

The resources employed are part-time work of task leader Prof. Jean-Pierre Changeux, and project manager Benjamin Simmenauer. This team will write a call for tenders (following the appropriate IP standard procedure) and choose a contractor (research institute) for the online platform and the recruitment of participants since these two services are not available at IP. The project manager will moderate the debates. The task leader and project manager will work on the survey reports together.

4.1.5 Measuring performance and progress in T12.3.1

Task	Indicator	Target	Date (Month)
T12.3.1	Number of participants in 1st HBP on-line deliberation (on Future Medicine)	100	M18
T12.3.1	Number of participants in 2nd HBP on-line deliberation (on Future Neuroscience)	100	M26
T12.3.1	Number of participants in 3rd HBP on-line deliberation (on Future ICT and Robotics)	100	M30

Table 13: Numerical indicators for T12.3.1

4.2 European Citizens' Conventions (T12.3.2)

4.2.1 Objectives

The goal of T12.3.2 (Lars Klüver, Danish Board of Technology) is to involve European citizens actively in a broad and inclusive debate of the societal and ethical issues raised by the scientific work done in HBP. The citizen involvement will benefit the HBP in several ways:

1) Provide a platform that allows participating citizens to gain more knowledge on the work done in HBP along with the issues raised by HBP and to express their opinions on these
2) Promote wider debate of the efforts made in HBP through interest in the activities from media, social scientists etc., illustrating how HBP invites a public debate of its work in an open and transparent manner
3) Provide scientists a chance to get valuable input to their work in the form of informed public reactions and to let this input influence the continuous development of their research objectives and processes.

The results from the different Citizen Conventions will be fed back to HBP parties such as central management, relevant researcher groups in the consortium and the ELSA and REC and will be communicated to the public via a 'Citizen, Stakeholder and Expert Newsletter'.

4.2.2 Methods

Over the lifetime of the HBP, T12.3.2 will organise five Citizens Conventions using different methods for citizen engagement. These could be in the form of consensus conferences, interview meetings, scenario workshops, the World Wide Views methodology, self-organised meetings etc., depending on the objective.

The citizen conventions will differ when it comes to number of participants, timeframe for the activities, and involved actors other than citizens such as HBP researchers, external experts etc. The richness and accuracy of the information gathered through deliberative citizen involvement activities overcome many limits of 'traditional' public opinion surveys, allowing the participants enough time and information to gain a deep understanding and express sensible judgments. The goal is to gain insights about what citizens think of certain controversial matters, to unveil their political priorities, and to inform HBP about the general public's views on their work and suggested alternatives for action. By integrating well-balanced information with their own values, worldviews and life experience, citizens can express informed opinions and make thoughtful suggestions.

We will develop and describe these methods in the ramp-up phase. The first citizen convention will take place at the end of the ramp-up phase when the project's platforms are fully operational and the project is yielding its first scientific results. The description of the different activities and their goals will be detailed enough to function as a work plan, but at the same time flexible enough to let the development in the HBP affect which issues will be covered and which of the methods will be deployed to fit the issues best. This will allow the citizen involvement to be in sync with the general debate on brain research and the specific work done in the HBP project itself to ensure that the results of the citizen activities are relevant and useful.

4.2.3 Implementation

Task	Action	Date (Month)
T12.3.2	Framing: Development of a detailed process for the citizens' involvements in the rest of the ramp-up phase and the rest of the project. Process elements include: Methodologies to be used Issues to be covered Number of participants and their characteristics Countries where the activities will take place Information given to the participants before and during the activities Resources from other actors inside and outside the HBP to be included	M1 to M22
T12.3.2	Planning and execution of the first European Citizen's convention	M22 to M30

Table 14: Implementation of T12.3.1

4.2.4 Resources

The FT (Danish Board of Technology) has historically emphasised the importance of citizen participation in technological development, administrative planning, and political decision-making. In its 25 years of methodological development, the FT has built a world-class skillset for the facilitation of trans-disciplinary dialogue and solution-oriented research. The many years of experience has given the FT significant practical experience in the use of participatory methodology as well as a technical and scientific knowledge in a number of fields essential to gaining the recognition from all involved actors.

The researchers involved will be FT director Lars Klüver, project manager Nanna Engberg and senior project manager Anders Jacobi. Lars Klüver is the director of the Danish Board of Technology Foundation and is recognised as an international expert in technology assessment (TA) and foresight methodology, and has been advisor on a multitude of national and international research, foresight and technology assessment activities. Nanna Engberg has been the project manager of 10 citizen summits involving about 2000 participating citizens and more than 100 politicians. Moreover, she has been responsible for a number of parliamentary hearings, workshops and interview meetings. Anders Jacobi has comprehensive experience and knowledge within the area of Science, Technology and Innovation Policy and Jacobi has led several projects with sociological methods involving participation, expert consultation, interviews and questionnaire techniques, policy development and innovation processes.

4.2.5 Measuring performance and progress in T12.3.2

Task	Indicator	Target	Date (Month)
T12.3.2	Number of participants in the first Citizens' Convention	50	M30

Table 15: Numerical indicator for T12.3.2

4.3 Stakeholders' and Experts' Forum (T12.3.3)

4.3.1 Objectives

T12.3.3 (Lars Klüver, Danish Board of Technology) will create forums where HBP stakeholders and relevant experts can have a constructive dialogue with the researchers doing the core work in the project on the ideas, considerations and concerns arising from HBP research, discoveries and technologies. The dialogue between HBP and non-HBP actors aims to strengthen HBP researchers' understanding of the broader social, political, ethical, legal implications of their work. The HBP will raise questions of interest for researchers and experts in a wide range of fields, potentially causing controversies that can be anticipated by the forum debates. At the same time, the input from the activities should be close enough to the life scientists' reality and everyday work, so that they can apply it in their future work.

4.3.2 Methods

We will share the results from the different stakeholder activities with central management, relevant researcher groups, the ELSA and the REC, and communicate them to the public via a 'Citizen, Stakeholder and Expert Newsletter'. The stakeholder activities will make use of a broad range of different means of interaction including workshops, seminars and thematic webinars.

4.3.3 Implementation

The first area of stakeholder involvement will be future medicine, more specifically medical data federation and personalised medicine in a HBP context, followed by future neuroscience and future ICT/robotics. For each issue, activities will move from outlining the issues toward more specific and solution-oriented stakeholder involvement activities.

Table 16: Implementation of T12.3.1

Task	Action	Date (Month)
T12.3.3	Framing of the stakeholders activities on data collection and treatment in the HBP: Identification of major issues through desk research and dialogue with representatives of SP8 Medical Informatics, HBP management and key stakeholders Identification and involvement of the relevant stakeholders and experts Definition of the methods and detailed process and agenda for the three planned activities.	M1 to M6 (completed)
T12.3.3	2-3 hour webinar(s): different actors in the field set the stage through speeches at the virtual meeting. Focus will be on a scoping of the issues, questions, challenges, and concerns at stake.	M7
T12.3.3	One-day seminar in Copenhagen (about 30 participants): participants will be HBP researchers and non-HBP relevant stakeholder representatives and experts. A combination of speakers and group sessions resulting in report with a number of inputs and recommendation on further actions.	M9
T12.3.3	A smaller solution-oriented task force 2-day workshop with focus on developing even more concrete recommendations for actions in HBP research using medical data.	M12

Task	Action	Date (Month)

T12.3.3	Framing of the stakeholders activities on future neuroscience: Identification of major issues through desk research and dialogue with representatives of relevant SP's, HBP management and key stakeholders Identification and involvement of the relevant stakeholders and experts Definition of the methods and detailed process and agenda for the three planned activities. Activities held: The form and content of the activities evolve from broader scoping activities where the issues are outlined towards more solution-oriented activities providing input to future work done in HBP.	M12 to M21
T12.3.3	Framing of the stakeholders activities on future ICT and robotics: Identification of major issues through desk research and dialogue with representatives of relevant SP's, HBP management and key stakeholders Identification and involvement of the relevant stakeholders and experts Definition of the methods and detailed process and agenda for the three planned activities. Activities held: The form and content of the activities evolve from broader scoping activities where the issues are outlined towards more solution-oriented activities providing input to future work done in HBP.	M21 to M30

4.3.4 Resources

The Danish Board of Technology (FT) has historically emphasised the importance of citizen participation in technological development, administrative planning, and political decision-making. In its 25 years of methodological development, the FT has built a world-class skillset for the facilitation of trans-disciplinary dialogue and solution-oriented research. The many years of experience has given the FT significant practical experience in the use of participatory methodology as well as a technical and scientific knowledge in a number of fields essential to gaining the recognition from all involved actors. The involved researchers will be FT director Lars Klüver, project manager Nanna Engberg and senior project manager Anders Jacobi. Lars Klüver is the director of the Danish Board of Technology Foundation and is recognised as an international expert in technology assessment (TA) and foresight methodology, and has been advisor on several national and international research, foresight and technology assessment activities. Nanna Engberg has been the project manager of 10 citizen summits involving about 2000 participating citizens

and more than 100 politicians. Moreover, she has been responsible for a number of parliamentary hearings, workshops and interview meetings. Anders Jacobi has comprehensive experience and knowledge within the area of Science, Technology and Innovation Policy and Jacobi has led several projects with sociological methods involving participation, expert consultation, interviews and questionnaire techniques, policy development and innovation processes.

4.3.5 Measuring performance and progress in T12.3.3

Task	Indicator	Target	Date (Month)
T12.3.3	Number of external stakeholders involved in round 1 of stakeholders' forum (on Future Medicine): webinars, seminars and workshops	20	M18
T12.3.3	Number of HBP researchers involved in round 1 of stakeholders' forum (on Future Medicine): webinars, seminars and workshops	10	M18
T12.3.3	Percentage of HBP researchers involved in the stakeholders' forum (on Future Medicine: webinars, seminars and workshops) deeming the input useful for their future work in HBP	75%	M18
T12.3.3	Number of external stakeholders involved in round 2 of stakeholders' forum (on Future Neuroscience): webinars, seminars and workshops	20	M26
T12.3.3	Number of HBP researchers involved in the round 2 of stakeholders' forum (on Future Neuroscience): webinars, seminars and workshops	10	M26
T12.3.3	Number of external stakeholders involved in the first round of stakeholders' forum (on Future ICT/Robotics): webinars, seminars and workshops	20	M30
T12.3.3	Number of HBP researchers involved in the first round of stakeholders' forum (on Future ICT/Robotics): webinars, seminars, workshops	10	M30

Table 17: Numerical indicators for T12.3.3

5. Researcher Awareness (WP12.4)

WP12.4 (Bernd Carsten-Stahl, De Montfort University) aims to encourage and foster ethical and social reflection among HBP researchers (including those early in their career), clinicians and technology developers by exploring their perceptions of ethics, the role of

the project in society and of responsible innovation. WP12.4 seeks to help all HBP researchers to be alert to ethical and social issues and to raise them in appropriate forums.

5.1 Ethical and Social Perceptions in the HBP (T12.4.1)

5.1.1 Objectives

The objectives of WP12.4 are:

- Define the ethical and social issues facing the HBP as identified by management through interviews, and by consulting SP12: Ethics and Society
- Survey HBP researchers to determine the extent to which these ethical and social issues are considered relevant
- Investigate key issues raised by the survey in-depth and to produce short position papers
- Identify teaching, training and educational needs.

5.1.2 Methods

WP 12.4 will use the following research methods:

- Qualitative semi-structured interviews of HBP directors and senior leaders, as well as individuals engaged in research raising specific issues
- Web-based surveys of all HBP researchers
- (Reflective) workshops
- Focus groups

5.1.3 Implementation

Task	Action	Date (Month)
T12.4.1	Identification of ethical and social issues by management	M3 to M7
T12.4.1	Survey of HBP Researchers	M13 to M16
T12.4.1	In-depth investigation of issues using focus groups and interviews	M15 to M30
T12.4.1	Reflective workshops	M15 to M30
T12.4.1	Teaching, training & education	M15 to M30

Table 18: Implementation of T12.3.1

The implementation of each goal is highly dependent on the results of preceding items, thus the following sections cover the proposed methods without further elaboration.

5.1.3.1 Identification of ethical and social issues by management

The directors and subproject directors of the Human Brain Project will be invited to participate in 30-minute qualitative interviews. These surveys will seek participants' views on ethics and responsible research and innovation (RRI) to their area of responsibility. We will obtain consent for further interviews as necessary.

After obtaining local and WP12.5 REC ethical permission, (February 2014) 24 directors and subproject directors have been invited and reminded to participate in interviews. Sixteen (75%) have agreed to be interviewed and six remain to be personally contacted to arrange an interview. Of the 18 directors, 10 (56%) have completed their interviews. These are currently being transcribed and analysed.

After an interim report of the findings has been compiled (April 2014), we will create a final list of social and ethical issues based on the results of our initial research. At this stage, it may be necessary to review certain items with management. The process of obtaining these further interviews will be identical to the process described previously. We will write a final report detailing the ethical and social issues identified by management and SP12 by June 2014.

5.1.3.2 Survey of HBP researchers

In October 2014, we will conduct an online survey of all HBP researchers using an appropriate tool that they can access securely. This will need to be specified, installed, piloted and implemented in advance.

Questions will include whether and to what degree the ethical concerns identified in the interim report are perceived to be relevant. In addition, we will gather personal data about nationality, culture, discipline and demographics. There will be an open section in which respondents will be encouraged to raise new issues. Respondents will also be asked about willingness to engage in further activities such as interviews and workshops, and willingness to serve as experts in public engagement or respondents for foresight purposes.

We will analyse the data by respondent type (determined using the demographic data) and identify areas where more detailed work is required. We will make survey results available to the other SP12 work packages so that they may explore questions pertinent to their research interests.

5.1.3.3 In-depth investigation of issues using focus groups and interviews

Depending on the outcome of the survey, particular issues will be investigated in more depth using qualitative research methods, such as interviews with specific researchers and focus groups. This research will lead to the development of short position papers on particular ethical issues. The precise number is dependent on the results of prior work but current data suggest, tentatively, that we will definitely write one such paper and maybe up to three. In principle, each will be supported by at least three interviews or one focus group. The final choice of method will depend on the topic and the number of researchers involved, as determined by the survey.

5.1.3.4 Reflective workshops

These workshops will ask HBP researchers to reflect on their practice, on their understanding of the ethical issues and how they might address them. We will prepare the workshops in collaboration with the subproject's management. The number and format of the workshops will depend on prior work, the issue being raised and the wishes of the management team. Current data suggest that we will require at least one such workshop and maybe three. However, at the time of writing, these are tentative estimates subject to change.

Topics for workshops will be determined by criteria such as relevance, and contentiousness. Indicative definitions of the selection criteria will be developed on the basis of a final report and refined following the survey of HBP researchers, as well as the interviews and focus groups.

5.1.3.5 Teaching, training & education

This work package is likely to identify areas where researchers are in need of further training and education. Possible topics might include research ethics, conceptual understanding and principles of RRI. Additions are expected as the research progresses. WP12.4 will write a short briefing note identifying educational needs as the basis for liaison with the HBP education programme to identify training needs.

5.1.4 Resources

All objectives for Months 1-30 will be met by a principal investigator (Professor B C Stahl) and a research fellow. Professor Stahl is the director of De Montfort University's Centre for Computing and Social Responsibility, a key player in an international research network investigating the social and ethical implications of ICT. He has particular expertise in computer and information ethics, emerging technologies and responsible research and innovation. The research fellow, Mark Shaw, was appointed in October 2013 and has expertise in quantitative and qualitative research, epidemiology, medicine, computer science and health informatics.

5.1.5 Measuring performance and progress in T12.4.1

Task	Indicator	Target	Date (Month)
T12.4.1	Number of qualitative interviews with management	75%	M7
T12.4.1	Number of respondents to online survey	30%	M16
T12.4.1	Number of focus groups (during the in-depth investigation programme)	2	M30
T12.4.1	Number of interviews (during the in-depth investigation programme)	9	M30
T12.4.1	Number of reflective workshops	1	M30

Table 19: Numerical indicators for T12.4.1

6. Ethics Governance and Regulation (WP12.5)

WP12.5 (Abdul Mohammed, Linnéuniversitetet) aims to support HBP decision-making on issues with significant social and/or ethical implications, and to help ensure that the project fully complies with European and national legal and regulatory requirements. As part of this work, WP12.5 will coordinate the HBP's participation in planned ethical reviews. We will submit documentation for reviews in Month 8 (first review) and Month 30 (second review).

WP12.5 will support the HBP's Ethics, Legal and Social Aspects Committee (ELSA) and Research Ethics Committee (REC), with respect to both their establishment and regular operation, as described in the section on implementation. The ELSA Committee will support HBP management on issues of policy and strategy. The REC is an advisory committee that will assist with enquiries to support local research sites on regulatory issues and compliance. Both committees will form *ad hoc* groups as needed to discuss specific issues; and, will maintain an agile responsiveness and alertness to potential, unexpected ethical, legal and social issues that may arise during the lifetime of the project. Organisational strategies for committees and working groups employed in this WP will reflect current best practice with regard to procedural and practical ethics governance and regulatory issues.

WP12.5 will also maintain an ethics data registry and take responsibility for communicating the official project position on specific issues in research ethics. The latter will include maintaining an information and interactive website on ethics procedures to support research ethics approval processes.

6.1 Ethical, Legal and Social Aspects Committee (ELSA) (T12.5.1)

6.1.1 Objectives

The aim of T12.5.1 (Kevin Grimes, Karolinska Institutet) is to support the independent Ethical, Legal and Social Aspects committee (ELSA). ELSA will provide strategic oversight of ethical, legal and social issues. It will act in an advisory capacity to the HBP Assembly and the HBP Governing Board, acting on its own initiative or in response to specific requests. Where it believes useful, the committee may also formulate recommendations for national and European regulators and raise issues it believes should be the object of broad public debate.

6.1.2 Methods

The Committee, which will have an initial term of office of five years, is composed of twelve members, includes members from the major currents of thought present in European society, and represents a broad range of competencies including law, medicine, science, and information and communications technology, including robotics. Where the Committee believes that the current membership is unbalanced or insufficiently representative or that it lacks key competencies, it has the power to appoint additional members.

6.1.3 Implementation

Task	Action	Date (Month)
T12.5.1	Selection of committee members and set up of ELSA	M1 to M6 (completed)
T12.5.1	ELSA in operation	M6 to M30

Table 20: Implementation of T12.5.1

Month 1-6 Selection of committee members and set up of ELSA

The selection of committee members has been completed. The selection followed a four-stage procedure aimed to guarantee the maximum possible competence, transparency and representativeness. The procedure was as follows:

- SP12 proposed formal criteria for choosing nominees to the committee that were approved by the HBP Governing Board. According to these criteria, the ELSA Committee should include at least 12 members (additional members may be chosen if needed). The selection was based on the following selection criteria

  1. Gender balance: approximately 50% of the members should be women

  2. Geographical balance: the committee should include members from all of the main countries participating in the HBP, and all of the main geographical and cultural areas in Europe (Western Europe, Eastern Europe, Southern Europe, and Northern Europe; see map below)

  3. "Main schools of thought" - the committee should include members from each of the main schools of thought present in European society. Members of the committee will belong to a broad range of religions, ideologies and political beliefs.

However the committee should not include official delegates from any particular grouping.

4. Balance of competencies - the committee should include a broad range of competencies including competencies in the natural sciences (especially biology, cognitive psychology and neuroscience), the social sciences, computer science, law, medicine, and privacy/data protection.

- The HBP External Advisory Board (EAB) and the Presidents' Advisory Council (PAC) each proposed a list of six nominees to comprise an ad hoc Selection Committee, three members from EAB and three from PAC. The Selection Committee invited nominations for candidate members for the REC. HBP Partners were encouraged to invite candidates, as well as organisations and individuals involved in the HBP, and other interested individuals and organisations.
- The Selection Committee reviewed materials received from candidates, applied matching criteria, and determined its selections. It then proposed to the Commission its list of nominees for the ELSA Committee.
- The Commission, by authority of the Policy and Program Officer, approved the full list of nominees. In addition it requested that an additional member, with expertise in the field of data protection, be added within a reasonable time to the ELSA Committee.
- The HBP General Assembly will submit the proposal for approval.
- All members of ELSA are acting in a voluntary capacity, except for the HBP T12.5.1 Secretariat (permanent staff from Karolinska Institutet and Linnéuniversitetet). The supporting Secretariat, independent of HBP central management, will organise meeting dates and logistics, facilitate committee startup, and provide ethics educational support. In addition, the Secretariat will provide training as needed, assist the Chair who has responsibility for meeting agendas, and contribute to writing and editing documentation. The Secretariat will be responsible for coordinating those aspects of the HBP's participation in the planned ethical reviews that fall within the remit of the ELSA.
- Linkages are an essential part of the overall strategy. Consistent with its advisory and independent role, ELSA interacts with both the HBP Board of Directors and the GA primarily by the normal course of bidirectional communications, such as quarterly reports, responding to requests for advice; and also, ELSA members have access to project information that is normally necessary to examine ethical, legal and social aspects of project results or anticipated results.
- ELSA and REC share reciprocal reporting responsibilities, including minutes and reports. In addition, semi-annually, ELSA and REC will conjoin for a session during their meetings in order share ethical content.
- ELSA is linked with each of the SP12 WPs, which may involve collaborative work on examining an ethical issue. WPs may request review of issues by ELSA, and vice versa. ELSA may request attention to an issue by the WPs, for example, to deepen understanding, bring to a wider audience, or investigate further.

Month 6-30: ELSA in operation

- The Committee will meet in plenary sessions twice per year, arranging its own calendar and agenda, and electing its own chairman. During the plenary meetings,

the committee will identify issues that require further attention and appoint Working Groups to examine them in depth.

- Working Groups will formulate draft recommendations, which the committee will formally adopt, or reject. Where the Committee or the Working Groups believe this could be useful for their work, they will organise hearings, in which HBP managers and scientists and invited experts from outside the Consortium will present and answer questions about specific areas of HBP strategy, research and technology development.

6.1.4 Resources

Kevin Grimes, Clinical and Forensic Psychologist, is Research Coordinator at Karolinska Institutet and is leading task T12.5.1. He has consulted on practical and procedural ethics in clinical, legal and academic settings. Christine Mitchell, Associate Director of Clinical Ethics in the Division of Medical Ethics at Harvard Medical School developed and runs the annual Harvard Bioethics Course. Shamim Patel, Chartered Accountant, was Project Manager of the EC, FP6 flagship project CHRISGAS, for 5.5 years, with 20 partners and a budget of €17 Pr. Abdul Mohammed (see REC resources, below) is also collaborating on this task.

6.1.5 Measuring performance and progress in T12.5.1

We will measure progress and performance in T12.5.1 by using the set of indicators detailed in the Table 21 below:

Task	Indicator	Target	Date (Month)
T12.5.1	Number of ELSA meetings	5	M30
T12.5.1	Number of working groups appointed to examine issues	2	M30
T12.5.1	Number of approved Ethical Reviews conducted by the Commission	2	M30

Table 21: Numerical indicators for T12.5.1

6.2 Research Ethics Committee (REC) (T12.5.2)

6.2.1 Objectives

The aim of T12.5.2 (Abdul Mohammed, LNU) is to support the REC. The REC will define and interpret standards for ethical conduct of research, and evaluate the status of research to ensure that HBP research meets the highest possible ethical standards and that it reasonably complies with relevant European, national and regional law, as well as with the ethical standards imposed by relevant professional bodies.

6.2.2 Methods

The six-member Research Ethics Committee (REC) is advisory. It will help Partners by advising on project applications to local ethics committees. This may include assisting

applications being challenged, as well as communicating and following up with ELSA and SP12 WPs about any issues that may arise. The REC, via its supporting Secretariat, will query individual research projects to identify projects involving animal experimentation, clinical data or human participants. REC's role is to offer advice and provide assistance to resolve ethical issues. Local ethical bodies, and relevant governmental bodies, have the authority to approve, disapprove or remedy the request being made for ethical approval; however, REC, has no authority to approve or disapprove, but will act in an advisory capacity.

The REC will choose a Chairperson, and a Vice-Chairperson, roles which are voluntary, and to be rotated among the members over the 5 year periods.

The HBP REC will be transparent so that the Public, Partners, and collaborators will be aware of how the committee functions and how it can be helpful, as well as what it is not responsible for.

6.2.3 Implementation

Task	Action	Date (Month)
T12.5.2	Selection of committee members and set up of REC	M1 to M6 (completed)
T12.5.2	REC in operation	M6 to M30

Table 22: Implementation of T12.5.2

Month 1-6 Selection of committee members and set up of REC

The selection of committee members has been completed. It followed a four-stage procedure that aimed to guarantee the maximum possible competence, transparency and representativeness. The procedure was as follows:

- The SP12 proposed formal criteria for choosing nominees to the committee that were approved by the HBP Governing Board. According to these criteria The REC should The **REC should consist of 6 members** chosen on the basis of the following criteria

  1. Gender balance: approximately 50% of the members should be women

  2. Geographical balance: the committee should include members from all of the main countries participating in the HBP, and all of the main geographical and cultural areas in Europe (Western Europe, Eastern Europe, Southern Europe, Northern Europe)

  3. "Main schools of thought" - the committee should include members from each of the main schools of thought present in European society. Members of the committee will belong to a broad range of religions, ideologies and political beliefs. However the committee should not include official delegates from any particular grouping.

  4. Balance of competencies - the committee will include a broad range of competencies including competencies in law, medicine, medical research, animal experimentation, and privacy/data protection.

- The HBP External Advisory Board (EAB) and the Presidents' Advisory Council (PAC) proposed a list of six nominees to comprise an ad hoc Selection Committee (as above, see ELSA), three members from EAB and three from PAC. The Selection Committee invited nominations for candidate members for the REC. HBP Partners were encouraged to invite candidates, as well as organisations and individuals involved in the HBP, and other interested individuals and organisations.
- The Selection Committee reviewed materials received from candidates, applied matching criteria and determined its selections. It then submitted its proposal of nominees for the REC to the Commission.
- The Commission, via the Policy and Program Officer, approved the full list of nominees.
- The HBP General Assembly will submit the proposal for approval.
- All members of the REC are acting in a voluntary capacity, except for the HBP SP12.5.2 Secretariat. The supporting Secretariat, independent of HBP central management, will organise meeting dates and logistics, facilitate committee start up, provide ethics educational support and training as needed, take responsibility for meeting agendas and assist in writing and editing committee reports. The Secretariat will be responsible for coordinating those aspects of the HBP's participation in the planned ethical reviews that fall within the remit of the ELSA, including monitoring project applications to local ethics committees, assisting where applications are challenged, communicating and following up with ELSA and SP12 WPs about issues that may arise. Linkages are an essential part of the overall strategy. One such linkage is with the SP12 WPs, and involves mutual work on examining an ethical issue. Linkages with HBP Board and GA are primarily the normal course of operations, including quarterly reports. ELSA and REC have reciprocal reporting, including minutes and reports.

Month 6-30: REC in operation

- Quarterly meetings: the work of the REC will include preparing and revising guidelines, assisting with enquiries in regard to ethics, responding to researcher queries, and mandatory reviewing HBP research ethics applications in association with any new 'open' calls.
- The REC will be supported by a permanent staff from the HBP Ethics and Society Division. The staff will organise meetings, keep track of changes in national and European regulations, and provide regular information on these changes to committee members and to HBP research groups. The staff will also maintain a website and a secure database containing details of past and on-going ethics applications (successful and unsuccessful) and communications with IRBs. Parts of this database will be made available to the public. The secretariat will be responsible for coordinating those aspects of the HBP's participation in the planned ethical reviews that fall within the remit of the REC.

6.2.4 Resources

Abdul H. Mohammed, Karolinska Institutet, Professor of Biological Psychology at Linnaeus University is leading task T12.5.2. He is a member of IBRO´s "Ethics in Research Committee" which formulates IBRO´s guidelines for the ethical use of animals in bio-medical experimentation and the ethics of scientific experimentation. Barbara J Sahakian,

Professor of Clinical Neuropsychology, University of Cambridge, is President of the International Neuroethics Society and Co-editor of The Oxford Handbook of Neuroethics. Shamim Patel, Chartered Accountant, was Project Manager of the EC, FP6 flagship project CHRISGAS, for 5.5 years, with 20 partners and a budget of €17 M. Kevin Grimes (see ELSA resources, above) is also closely collaborating on this task.

6.2.5 Measuring performance and progress in T12.5.2

Task	Indicator	Target	Date (Month)
T12.5.2	Percentage of permits received from the HBP partners whose work involves animals / humans	100%	M3
T12.5.2	Percentage of renewed or updated permits received from the HBP partners whose work involves animals/ humans	100%	M30
T12.5.2	Number of REC meetings	9	M30
T12.5.2	Percentage of applications (received in open calls for potential ethical issues) reviewed and assessed	100%	M30
T12.5.2	Number of approved Ethical Reviews conducted by the Commission	2	M30

Table 23: Numerical indicators for T12.5.2

The process of getting 100% of the ethical permits has been completed in Month 3, as expected.

7. Ethics and Society: Scientific Coordination (WP12.6)

The aim of WP12.6 (Jean-Pierre Changeux, Institut Pasteur) is to coordinate the HBP Ethics and Society subproject, ensuring that the work is efficiently organised and documented and that the research contributes to the overall goals of the project. There is only one task in this WP12.6: T12.6.1 - Scientific coordination and support.

7.1 Scientific Coordination and Support (T12.6.1)

7.1.1 Objectives

T12.6.1, led by the Subproject Leader (Jean-Pierre Changeux, Institut Pasteur), coordinates and monitors the development of the Ethics and Society Subproject (WP12.1-12.5), supervising the progress of work in the different SP12 work packages. This task includes checking that the activities described in the Research Plan are performed in a timely manner (according to the given schedules). It will audit the SP12 partners' contributions, that they meet HBP requirements and quality standards. And it will make sure that the research done in SP12 is complementary among the work packages and is performed continuously, coherently and interactively.

T12.6.1 will thus coordinate the planning of the research and define the indicators used to measure progress and quality, and their target values (content of D12.6.1), making regular

progress reports to central management, representing SP12 in meetings of the HBP Board of Directors (BOD) and leading the implementation of BOD and Executive Committee (ExCo) decisions within the subproject.

7.1.2 Methods

T12.6.1 will be responsible for organising the work of the SP12 subproject committee, fixing the agenda for meetings and leading scientific and technical discussions. Between subcommittee meetings, T12.6.1 will lead regular discussions among subproject researchers through regular audio/video conferences, face-to-face meetings, workshops, and the other communications facilities provided by the project such as the internal website. T12.6.1 will be responsible for reviewing the quality of work package contributions to deliverables, applying the methodology described in Part B 1.2.2.1 of the DOW and the specific indicators defined in the present document, and for proposing corrective action where this is required. T12.6.1 will be responsible for planning, assembling, and editing all reports to be produced by the subproject, for organising the review process, and for ensuring their timely release. This task is also responsible for all quarterly reporting within the SP, including delivery of SP written report. And T12.6.1 will coordinate the planning of SP12 scientific activities for the operational phase.

T12.6.1 will also organise conferences bringing together scientists from the HBP main areas (ICT, medicine and neurosciences) and researchers in social sciences, philosophy and ethics in a series of public academic meetings. Each conference will consist of science talks on a significant aspect of HBP current research, and a discussion of ethical and conceptual aspects with members of the SP12 group.

7.1.3 Implementation

Table 24: Implementation of T12.6.1

Task	Action	Date (Month)
T12.6.1	Monitor the performance of the other work packages, controlling the quality of their output, integrating these outputs into deliverables (in most cases reports, or prototypes of technical systems), and providing a summary of the results.	M1 to M30
T12.6.1	Internal SP12 workshop at the HBP Summit 2013 (8-9 October 2013) at EPFL Lausanne on coordination among work packages	M1 (completed)
T12.6.1	Cross-meeting SP8 (Medical Informatics) with SP12 at EPFL Lausanne on the question of informed consent for use of data in hospital archives (9 October 2013)	M1 (completed)
T12.6.1	Meeting of SP12 representatives with the EPFL team for developing the HBP portal on SP12 web tools' requirements and their implementation roadmap (10 October 2013)	M1 (completed)
T12.6.1	WP12.1, WP12.3 and WP12.4 workshop at King's College London: follow-up of the HBP Summit 2013 internal SP12 workshop on coordination among work packages (3 December 2013)	M3 (completed)
T12.6.1	Edit the SP12 website (delivery of a first version of the site expected on Month 3)	Not completed yet (HBP portal delayed)
T12.6.1	First SP12 conference on neurotechnological assessments of consciousness (including ethical and societal aspects) in collaboration with members of SP3 (February 27-28, Institut Pasteur)	M5 (completed)
T12.6.1	Write Ethics and Society research plan	M6 (completed)
T12.6.1	Edition of a public 'Ethics and Society in HBP' website for public information and communication.	M6 to M12

Task	Action	Date (Month)
T12.6.1	Second SP12 conference on simulation in collaboration with members of SP6 (June 26, Institut Pasteur).	M9
T12.6.1	Write Ethics and Society progress report	M12
T12.6.1	Third SP12 conference on brain diseases and disorders with members of SP8 (September 29, Heidelberg)	M12
T12.6.1	Fourth SP12 conference on consciousness and self-consciousness in collaboration with members of SP3	M17
T12.6.1	Evaluation of D121.1 (The HBB Foresight Lab: first report of future medicine)	M17
T12.6.1	Write first Ethics and Society report	M18
T12.6.1	Fifth SP12 conference on cognitive enhancement with members of SP3	M21
T12.6.1	Evaluation of D121.2 (The HBB Foresight Lab: first report on future neuroscience)	M23
T12.6.1	Sixth SP12 conference on memory manipulation with members of SP3	M25
T12.6.1	Evaluation of D121.3 (The HBB Foresight Lab: first report on future computing technology, including robotics)	M29
T12.6.1	Seventh SP12 conference on cultural circuits in the brain and simulation with members of SP6	M29
T12.6.1	Write second Ethics and Society report	M30

7.1.4 Resources

The resources employed on a part-time basis include task leader Prof. Jean-Pierre Changeux, and Project Manager Benjamin Simmenauer. Prof. Changeux is renowned worldwide as a neuroscientist and headed the National Advisory Committee on Bioethics in France from 1992 to 1998. Benjamin Simmenauer, trained in Philosophy and Mathematical Logic, has worked as Project Coordinator for the HBP Society and Ethics group during the preparatory phase. Each will collaborate with the SP12 entire group on the T12.6.1 objectives, and especially with Kathinka Evers who is SP12 Co-director.

8. Addendum to D12.6.1

8.1 Introduction

The HBP Review in January 2015 required a number of changes to SP12 processes and activities. These requirements have informed an on-going debate within SP12 and led to a number of changes.

SP12 will have to provide individual responses to the various reviews and EC documents. As these will refer in many cases to the same questions, this addendum provides a summary description of the various changes instituted by SP12. The addendum has been agreed by the SP12 Steering Committee. It will form a shared part of all responses to the EC.

8.2 Changes to SP12

SP12 fully recognises the importance of the points raised by the review, and addresses them as outlined below.

The ethics management and compliance aspect of SP12 will be reorganised and strengthened with immediate effect. The main aspects of this reorganisation are:

8.2.1 Merging of REC and ELSA into the Ethics Advisory Board with Immediate Effect

- The Ethics Advisory Board (EAB) is the HBP's independent body responsible for advising the HBP Board of Directors (Board) on specific ethical, regulatory, and social issues raised by research that is being undertaken or planned under the auspices of the Human Brain Project. Under authority delegated by the Board, and coordinated with the Ethics Manager (see below), the EAB may communicate with individual researchers, and should enjoy open access to information about the Project. When it deems necessary, the EAB may advise the Board on the preparation and implementation of monitoring and auditing.
- The advisory status of an EAB recommendation implies that individual researchers, investigators, laboratories and institutions will retain their legal responsibilities under the terms of local, national and international regulations, as well as professional obligations in place from time to time.
- The EAB's access to SP12 scientific and engagement data and results, and other information and resources, is managed by the SP12 Ethics Manager (see details below). In anticipation of its deliberations, the EAB may request that SP12's scientific attention be brought to specific areas of special interest, which may call upon scientific research, public engagement or philosophical inquiry.
- The collaboration between the EAB and SP12 is facilitated by the Ethics Manager, who normally coordinates communications regarding requests made by the EAB. However, the EAB is privileged to communicate with the Board directly when it deems necessary.
- The Ethics Manager is part of SP12 and is an *ex officio*, non-voting member of the Board of Directors. Unless the EAB Chairs object, the Ethics Manager will also participate as a guest at EAB meetings.

- The Ethics Manager will ensure that each HBP SP appoints at least one Ethics Rapporteur (ER) to liaise between that researcher's own SP and the EAB. This ER is responsible for facilitating open communication between the EAB and the management of on-going HBP research. A member of the EAB will be assigned to each ER in order to ensure rapid communication. ERs may raise any actual or potential ethical or societal issues with the EAB; and ERs are expected to communicate to their parent SPs the EAB's views and opinions regarding the management of research within that SP.
- The EAB will advise on its own initiative as well as in response to requests made by ERs, researchers, or other members of the HBP, about specific ethical, regulatory, and social issues arising from research undertaken within the HBP or research undertaken by third parties when the results of this research will contribute to the HBP. It may issue guidance to researchers on such issues as may arise in future research.
- Examples of the issues that the EAB will address include the use of human and animal research subjects, data protection, informed consent, use and misuse of research, as well as short- and long-term social implications of the research.
- Output:
  - Annual Report of EAB Activities: The EAB's main output is advice and recommendations to researchers and the Board of Directors on ethical, regulatory, and social issues in HBP research. Annual Report of its body of work, including a profile of requests and summary opinions is to be issued and delivered to the Board.
  - Annual Ethics Rapporteur Workshop: WP12.4 will report on its collaboration with the EAB to plan, conduct and evaluate an annual "Ethics Rapporteur Workshop". Evaluation will incorporate i) identifying ethics, regulatory, philosophical and social issues relating to the research plan into the future; ii) obtaining quality ratings. In collaboration with the Ethics Manager, SP12 will perform research to support the EAB's review and recommendation role, and will provide other resources that support the work of the Board.
- Dissemination:
  - The EAB may disseminate opinions and seek to motivate opinion through publishing summaries of its deliberations, opinions and recommendations in scientific publications.
- Standard Operation Procedures (SOPs)
  - The Ethics Manager will coordinate the planning and implementation of Standard Operating Procedures.
  - The number of members of the EAB shall be determined primarily by the specific competencies that are needed. These will be determined, in part, by presence of known or expected issues, matched to the core competencies present within the EAB membership. When adding a member, selection should always ensure that core competencies are matched to the major scientific and technological foci of the HBP. The overall composition of the EAB should be balanced with respect to national representation, major currents of thought in European society and gender. The EAB will elect its leadership from among its members.
  - Members of the EAB will be appointed for an initial term of five years, renewable for another three-year term.

8.2.2 Creation of a Steering Committee (SC) of SP12 which serves as the main decision making body of the SP.

8.2.2.1 SC Tasks:

- Any necessary coordination to facilitate collaboration of SP12 Work Packages with one another, with other HBP Subprojects or with stakeholders and members of the public.
- Agreement on SP12 principles and management practices, e.g.
  - Collaboration
  - Communication strategy
- Requesting and monitoring the creation and functioning of standard operating procedures for PORE issues
  - It is expected that all WPs will contribute to the development and implementation of the SOP
- Coordination of responses to the EC for their ethical questions (led by the Ethics Manager)
- Management, allocation and monitoring of progress on PORE issues
- Ensuring that all events and outputs are clearly communicated internally and externally, in particular liaising with the HBP communications team.

8.2.2.2 SC Membership

- SP12 Leader
- One representative per WP
- Secretary

8.2.2.3 SC Activities

- Meetings
  - The SC meets at least monthly and ad hoc when required.
  - The Chair of the SC can call a meeting with three days' notice
  - Agenda and decision points have to be distributed at least 1 day before the meeting
- Decisions
  - The SC is quorate if three members are present
  - If necessary, decisions can be made with an absolute majority of members present in the meeting. In practice the best decisions will emerge from a consensus of members of the steering committee, be well communicated to SP12 as a whole, and be implemented after feedback and necessary deliberation has occurred.

8.2.3 Creation of an Ethics Manager position

The creation of an Ethics Manager position is SP12's solution to address ethics management issues, along with close collaboration between WP12.4 and WP12.5, with a view to merging them in the future.

8.2.3.1 The Ethics Manager's tasks:

- Represents ethics management issues on the HBP Board of Directors
- Interfaces with the European Commission
- Prepares responses to EC ethics reviews
- Provides required information to the EC
- Leads the HBP efforts of ethics audits
- Works with HBP general management to ensure that ethics management and SOPs are appropriately integrated in HBP management structures
  - Oversees the development of Standard Operating Procedures in collaboration with the EAB, SP12, SP11 and other bodies where required
- Works with all scientific SPs and ensures that ethics management issues are addressed appropriately:
  - Prioritises ethical issues raised by the Point of Registration (PORE) in collaboration with the SP12 Steering Committee and Ethics Advisory Board
  - Monitors compliance and analyses regular reports with ethics-related SOPs in all SPs
  - Oversees the Ethics Rapporteur programme
  - Contributes to the Education Programme to ensure it covers HBP ethics management
- Leads the ethics management team:
  - Develops and oversees ethics management processes
  - Ensures that relevant information (if not confidential) is publicly available
  - Updates the ethical issues map of the HBP
  - Represents ethics management in the data governance committee
  - Establishes links with related initiatives using big data in health-related research such as ELIXIR, BBMRI, EuroGentest and ECRIN to identify good practice.

8.2.3.2 The Ethics Manager's role in the HBP:

- The Ethics Manager will be an *ex officio* (non-voting) member of the Board of Directors to ensure that ethics management issues receive full support at the top level of the HBP (agreed by SP12 Steering Committee on 31.03.2015).
- Ethics management should be integrated into HBP management to ensure it is communicated to all SPs and compliance can be monitored and, where required, enforced.
- The Ethics Manager can request SP12 to focus research on specific issues which need more detailed attention.
- The Ethics Manager will be a member of SP12 (where subject expertise on ethics resides).
- The Ethics Manager will be a member of the SP12 Steering Committee.

- The Ethics Manager will lead the Ethics Management WP (see below).

8.2.3.3 Creation of a Work Package dedicated to Ethics Management:

The Ethics Management WP ensures that ethical issues are managed to highest standards within the HBP. Ethics (management) is one of the six components of Responsible Research and Innovation (RRI), along with public engagement, open access, gender equality, science education and research governance. This WP will work to ensure that insights from the research component of the SP are put into organisational practice in the HBP. The ethics management WP ensures that the HBP takes a leading role in defining best practice in dealing with ethics in brain simulation and big data in healthcare more generally. The WP will be formally created at the commencement of the FPA. During the remainder of the Ramp-Up Phase, the tasks of the ethics management WP will be fulfilled by close collaboration of WP12.4 and WP12.5 under the joint leadership of the Ethics Manager.

Each of the tasks listed below will be described in a more detailed document or SOP. These SOPs will be made available to the HBP, the EC and the public in an appropriate way.

8.2.3.4 Ethics management responsibilities:

8.2.3.4.1 Principles and Implementation of Ethics Management

Ethics management requires the coordination of the broad range of activities that are collected in this WP. Due to the fast changing nature of the research and technology within the HBP, the principles and implementation of ethics management need to be agile, in order to remain responsive to novel challenges. Task 12.4.1 will therefore focus on the continuing review and update of the principles of ethics management and the close collaboration of the WP team. It will furthermore be responsible for ensuring that input from the other WPs of SP12 are translated and made usable for the intended audience within the HBP. This task is the place where interaction between ethics management and the organisational structures of the HBP, notably the Board of Directors, take place. One important output of this task is the HBP map of ethical and social issues, which contains the summary of key issues raised by SP12, other members of the HBP and external stakeholders and outline how these are addressed and their further information can be found. This map will be made available on the SP12 website.

In order to ensure broad awareness of ethics management principles and practices, this task will contribute to the education programme of the HBP.

8.2.3.4.2 Standard Operating Procedures

An important aspect of RRI that sets it apart from previous attempts to systematically reflect on and influence the trajectory of science and technology development is its focus on practical relevance. Insights gained from research and the resulting recommendations need to be developed into practical and applicable standard operating procedures (SOPs) that can be implemented, monitored and enforced. This task will therefore focus on identifying candidates for SOPs, formulating such SOPs, consulting with relevant stakeholders, integrating them into broader HBP management structures and monitoring their impact.

SOPs will be the typical way in which the HBP can address recurring ethical and social issues. They were therefore be referenced in the map of ethical and social issues. All SOPs, once agreed via an appropriate process, will be made publicly available on the SP11 website.

8.2.3.4.3 Identification and management triage of ethical issues (PORE)

The Point Of Registration (PORE) is the place where social and ethical issues can be brought to the attention of the HBP. It is implemented as an online survey that allows interested parties to submit ethical and social concerns regarding the HBP. This task will collect issues, undertaken initial triage and propose appropriate responses that are then forwarded to the SP12 Steering Committee which decides on further actions, such as an evaluation by the EAB, the development of an SOP or external mechanisms. Where PORE identifies novel and relevant issues, these will be added to the map of ethical and social issues of the HBP.

8.2.3.4.4 Ethics Compliance

All research within the HBP is governed by European legislation and has to comply with national law and practices. In accordance with the principle of subsidiarity, the HBP relies on local ethics approval for all research undertaken within the EU. Any such research will need appropriate ethics approval from competent authorities. These approvals will be collected by this task to ensure ethics permissions are pertinent and valid. In cases where research is undertaken outside of the jurisdiction of the EU (e.g. in Switzerland or Israel), researchers will need to gain approval from the Ethics Advisory Board of the HBP (see task vii below). This task will facilitate the communication between researchers and the EAB and collect all relevant documents to ensure such research complies with EU requirements.

8.2.3.4.5 Interface with the European Commission

Much of ethics management is driven by EC requirements. This dedicated task will focus on communicating with the European Commission with a view to ensure quick responses, openness and transparency. Work undertaken in this WP includes:

- Preparation of responses to EC ethics reviews
- Provision of required information to the EC
- Leading of the HBP efforts of ethics audits

8.2.3.4.6 Management and Support of the Rapporteur Programme

The rapporteur programme brings together individuals from all SPs in a structured way to allow them to interact with the WP12.4 and the EAB on ethical issues that have arisen within research in the HBP. Specific ER Program Goals are to:

- Describe the activities of all SPs of the HBP
- Explain the results of research by other SPs
- Identify potential ethical, legal or social issues
- Make colleagues in their SP aware of the means by which they can communicate ethical, legal or social issues to ethics management
- Disseminate relevant SOPs in their respective SPs
- Support each other in the rapporteur role
- Report on the implementation and impact of SOPs.

8.2.3.4.7 Management and Support of the Ethics Advisory Board

The EAB is an independent body that provides ethics expertise to the HBP. This task provides the EAB with secretarial and administrative support.

The Ethics Advisory Board will take direct responsibility for ethical review of research whose conformity with relevant legislation and Horizon 2020 rules is not guaranteed by existing bodies and procedures. This includes research involving use of data, samples or resources generated outside the project or carried out in non-EU countries, data sharing agreements with third parties contributing data to HBP platforms (e.g. data sources for the Medical Informatics and the Neuroinformatics Platform) or using data provided by the platforms, proposals for partnering projects.

8.2.3.4.8 Budget

- The restructuring of the work undertaken in the previous WP12.4 and WP12.5 and the addition of a number of novel activities puts significant strains on the available budget. In order to address the budget issues two sources of savings have been identified:
  - Combination of WP12.4 and WP12.5 resources
  - Efficiency savings from merger of REC and ELSA

These savings and an improvement in efficiency will allow setting up the structure indicated above and preparing a fully functional ethics management system in preparation for the operational phase of the HBP.

While budget discussions are currently on-going, SP12 has agreed to invest any free budget into ethics management.

The budget of the ethics management WP will include EUR 10 000 per year for subcontracting to ensure short-term access to external ethics expertise where required.