Ethics Management and Responsible Research and Innovation in the Human Brain Project

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Abstract

Responsible research and innovation (RRI) is a key concept in current discourses concerning research governance and policy. The practice of Ethics Management in the European Union (EU) Future and Emerging Technologies (FET) Flagship Human Brain Project (HBP) utilises a concept of 'meta-responsibility' in order to further RRI. This chapter will explain the theory and practice of meta-responsibility to demonstrate RRI in practice in the HBP.

As a Flagship EC research project, the HBP represents a particular opportunity to espouse the best aspirations of the European research area. In this chapter, particular focus is given to responsible research and innovation as it is theorised and implemented within the HBP.

This article focusses specifically on the role and practice of ethics management in the RRI efforts of the HBP. As such, it presents a truncated and incomplete view. This is unavoidable, given the complex nature of the area – *the map is not the territory*. Other perspectives are possible, from which other aspects of RRI, and of the HBP overall, might gain or lose emphasis. Nevertheless, here is presented an ethics management perspective on, and role in, RRI so far in the HBP.

Why RRI?

The European Union is faced with a number of challenges, from long-term demographic issues to the ongoing financial and economic crisis. In the Europe 2020 strategy (European Commission, 2010), the President of the European Commission outlines how these challenges are going to be addressed. This will be done by following three mutually reinforcing priorities: smart growth, sustainable growth and inclusive growth. These three priorities are held to be possible only by relying on scientific and technical research. Research thus has achieved a central role for European policy. With this central role of research comes the question of the responsibility of research and its role in democratic societies.

Von Schomberg (2013) suggested a definition for responsibility in research that emphasises "… a transparent, interactive process in which societal actors and innovators become mutually responsible to each other …" Transparency and interactivity are linked explicitly with responsibility, highlighting the need for careful explication of these central concepts of participatory governance in the context of co-responsibility where innovative change is at work.

Emerging technological challenges clearly have implications beyond the field of science and technology alone. They are linked to political processes, wherein deliberation and participation is required, but also beyond these political circles. Thus, the situation calls for new and innovative modes of governance.

To put this differently, the EU, as well as most other political and economic powers, relies on innovation to achieve its policy goals. At the same time, the reach and impact of research and innovation is such that it can no longer be left to scientists and researchers alone. All citizens are stakeholders of research (Felt, Wynne, & others, 2007), partly because they provide required resources, partly, because they have to deal with the consequences. Left to its own devices, research can be blind to relevant social issues such as inclusion, justice or environmental concerns (Gallopín, Funtowicz, O'Connor, & Ravetz, 2001). Additionally, technology responding to societal needs is no longer produced by individual disciplines but is increasingly interdisciplinary in nature. The production of scientific knowledge is now often related to applications rather than 'pure' scientific curiosity (Gibbons et al., 1994).

With the background in policy, the need for RRI, and a hint at what it ought to be focussing on now outlined, the basis is provided on which to characterise the specific challenge for RRI and in particular for Ethics Management in the HBP.

The RRI challenge for the HBP

The HBP is a large project, with 112 Partners in 24 countries in Europe and around the world. These partners come from a wide range of disciplines, from sciences to the humanities; from the theoretical to the applied. These constitute the HBP by way of 13 subprojects (SPs), specialising in areas such as neuroscience, psychology, cognitive architectures, supercomputing neuroinformatics, robotics, and ethics and society. As such, there are a great many ways to conceive of the nature of the project, as well as its stakeholders, end users, potential beneficiaries, and so on. What's more, the picture can be dynamic, as progress is made, agendas re-shaped, and partners' roles re-cast. Von Schomberg's 'mutual responsiveness' condition may be seen as particularly useful in this context, because it can be read as having an inherently dynamic component.

Ethics Management as Part of RRI and Ethics and Society

A multiplicity of stakeholders must be invoked in order to establish a basis for responsible innovation in general, and specifically for the HBP, this will include very diverse groups. Not least, RRI must be carried out so as to establish the links between stakeholders in terms of responsibility bearers, responsibility *to what or whom*, and so on. This is crucial to the implementation of responsible innovation practices in the HBP.

The HBP has one entire sub-project (SP12) dedicated to research and practice concerning ethics and society. This SP which is the organisational home of RRI in the project is divided into four work packages. The division of labour with SP12 is inspired by Stilgoe et al.'s interpretation of RRI and its subsequent adaptation by the UK Engineering and Physical Sciences Research Council (EPSRC). The EPSRC has included RRI into its strategy by employing the AREA acronym, which stands for Anticipation, Reflection, Engagement and

Action. This framework is different to, but in creative tension with, the European Commission's own RRI framework which emphasises specific thematic elements of RRI – public engagement, open access, gender, ethics, and science education.[1] The interaction of these is a fruitful area for examination, but is out of scope for now in this chapter.

Anticipation as part of RRI in the HBP is undertaken by the Foresight Lab, which forms one work package of SP12. Conceptual and philosophical reflection is a second work package. The third work package is dedicated to engagement. The HBP furthermore undertakes work that falls under the EU's definition of RRI, such as work on gender awareness and science education which are located in the central management structure. In addition to the funded activities of the HBP, the project is given advice on ethical issues by the Ethics Advisory Board (EAB). The EAB consists of a number of independent experts who were selected on the basis of their subject expertise. They receive organisational support from SP12 but are fully independent. The EAB can react to issues conveyed to them by various bodies of the HBP, but it can also become active on its own initiative.

All of these various groups and bodies form part of the fabric of the HBP that is charged with ensuring that ethical and social concerns are recognised and addressed. They have undertaken much work which has led to a number of publications. In this chapter we will not have the space to discuss them in as much depth as they deserve, because we will focus on one particular component of RRI that we believe is firstly novel, and secondly needs to be discussed more widely, because it addresses a gap in the current RRI literature and practice. This component is what is called Ethics Management (EM). In the HBP EM is the fourth work package of the Ethics and Society SP. From our perspective EM has the purpose of translating the various activities of the other ethics-related bodies into practice. In terms of the AREA framework, EM focuses on the final A, the action, something that is currently under-emphasised in the overall RRI discourse. For the remainder of this paper we therefore focus on the theoretical underpinnings and practical activities of EM in the HBP.

What in theory?

It is important to bear in mind that researchers are always to be seen as responsible for their own research. Just as this is the case in terms of outputs, publications, patents, and so on, this too is it the case ethically. EM accordingly does not take solely a policing function in the HBP, but rather adopts a facilitation approach, managing the ethics responsibilities of researchers across the HBP. The idea is that flagship-wide ethical awareness is raised through communication with EM, and with researchers in subproject 12 (ethics and society) more widely, some of whose work relates to the HBP itself, its possible consequences, and its self-conception.

Once ethics issues are identified, as a result of this awareness raising activity as well as through the work of SP12 more widely, they can be discussed, addressed, and the process recorded for accountability and reflection. The process, moreover, is not one envisaged as with a built-in endpoint. Instead, reflection can be ongoing. This ensures ethical responsibility in terms of existing ethics issues with research (e.g. compliance with established norms) but

[1] See more at https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

also creates a dynamic process that can deal with emerging issues and unanticipated research developments. In this sense, the ethics management approach is a dialogical and deliberative one with similarities to discourse ethics (Apel, 1993; Habermas, 1996). .

EM's meta-responsibility approach suggests that the quality of the discourses on RRI and associated topics are the loci of responsibility. Those who take part in, contribute to, the discourse are charged with keeping these discourses of high quality. This means involving the correct people ensuring good questions are asked, pursued, and so on. Where the discourses fail, or fall short, action is needed and the shared responsibility of those who have contributed is activated. The propositions, the reasons, the concepts put into play are up for reinforcement, revision, rejection in the case where problems arise. A key issue is clearly that of responsibility itself.

In answer to the question, "who is responsible for ethics in the HBP?" the answer is given, "You are!" This is shorthand for the distributed nature of responsibility for research across the HBP. It also contains the germ of why ethics management is needed at all – if all are responsible; a locus for pursuing, documenting, facilitating, and capacitating this is required. Thus, again, meta-responsibility arises: EM takes on a responsibility for reflecting upon how this sort of management should be done, implements a plan, and assesses it in action. The responsibility taken on is one centred on others' responsibilities. The specific practicalities are to be described below. First, it is worth looking into the ideas at work.

As noted by Vincent (2011), 'responsibility' has various interpretations as far as it is ordinarily employed. These are capacity, causal, role, outcome, virtue, and liability responsibility. Given this discursive analysis of the common term:

> "To the extent that in ordinary discourse the term "responsibility" refers to a range of different concepts… responsibility theory can be applied in a range of practical contexts that use the term "responsibility" in these different ways – i.e. to help us resolve the sorts of problems that are encountered in public policy, in courtrooms and in other non-philosophical contexts."

The sort of meta-responsibility favoured by the EM team needs to consider at least these types of variation in meaning and connotation concerning responsibility. This requires that the nature of researcher involvement in EM processes is treated as of central importance. Recalling von Schomberg's take on RRI as a driver of research, and the six-fold division in the taxonomy of the responsibility concept (Vincent, 2011), we can remind ourselves of Apel (1993) on public responsibility as he discusses;

> "…the urgent need for a novel concept of *responsibility:* a concept that neither can be reduced to *individual accountability* nor allows for the individuals unburdening themselves from personal responsibility, by, e.g., shifting it into institutions or social systems. I suppose that the novel problem has emerged as a consequence of the human situation in today, and I would provisionally define it as that of *everybody's co-responsibility for the effects of collective actions or activities.*"

This sort of rationale motivates EM in much of its activities. Effectively, the aim for EM is to host high quality dialogues, including capacity-building exercises such as workshops, across

the HBP in any instance where ethics, responsible innovation, or any associated matter arises. Moreover, using the same apparatus that hosts these dialogues, EM aims to encourage reflexivity into the ordinary running of HBP research. This is of value in itself, of course, but especially in a large project with a variety of research, and potentially far-reaching consequences, reflexivity of this kind can anticipate future issues. The HBP can therefore provide insight into how complex, anticipatory governance of ethics and RRI issues can proceed.

Given these complex aims and ambitions, it is important to have arrangements in place that can facilitate them. These arrangements have to be capable of bearing the weights of ethics compliance, discourse on emerging issues, sharing insight across subprojects, and so on. The next section gives some detail on the actual arrangements in place.

How in practice?

The processes of ethics management have high ambitions placed upon them, not least by the research funders. Nevertheless, this is a large, actively changing project. EM has to be open to correction and self-critique. Besides the high ambitions and self-reflexivity for ethics and for RRI in the HBP, the processes must have a starting point, and one that can capture in a fundamental way the state of the art in the project as a whole. In the first instance, EM uses questionnaires based upon H2020 self-assessment criteria and reflection upon HBP ethics reviews in order to first establish a baseline of ethics issues.

Self-assessment

Across the entire HBP, these questionnaires are distributed at the task level. The issues range from easy to anticipate biomedical research ethics questions, such as the treatment of animals and human subjects in research, to questions of data protection in the federated technical infrastructure, to complex questions of the possibility of machine consciousness and human identity. Responses to the surveys are recorded and classified by ethics management, and where ethics issues arise, they are given actions for follow up. In cases of animal research, for instance, approvals are requested from the researchers involved, to ensure compliance. Ethics management collects all of the issues, tracks them, assigns actions, and monitors the way they are addressed.

This is a primary mode for how ethical issues can be identified, analysed and addressed in the HBP. Given the size and complexity of the HBP and the numerous ethical issues it can and does raise, it is crucial to have mechanisms that allow more fine-grained activity. Playing a central role here is the HBP Ethics Map.

Ethics map and action plans

Ethical issues can be added to the HBP Ethics Map through a variety of ways. Their origins may be from research itself, suggestions made by collaborators, submissions made via publicly accessible ‘PoRE’ mechanism (see below) or from European Commission reviews. The inclusion of new items to the HBP Ethics Map is proposed by the Ethics Manager and discussed by the SP12 Steering Committee.

The ethics map is a useful document that can represent visually a snapshot of the present issues at play in the HBP. The map shows a snapshot of the likelihood of ethics issues arising, along with their expected social impact. This is based on exercises taken from within the consortium, as well as from more general research. More regulated areas of HBP research tend to be thought of as having low likelihood of arising as ethics issues, owing to their familiar role in research. Unregulated activities tend to appear as having high impact and high likelihood of arising. Below is a highly simplified illustration of the ethics map in principle:

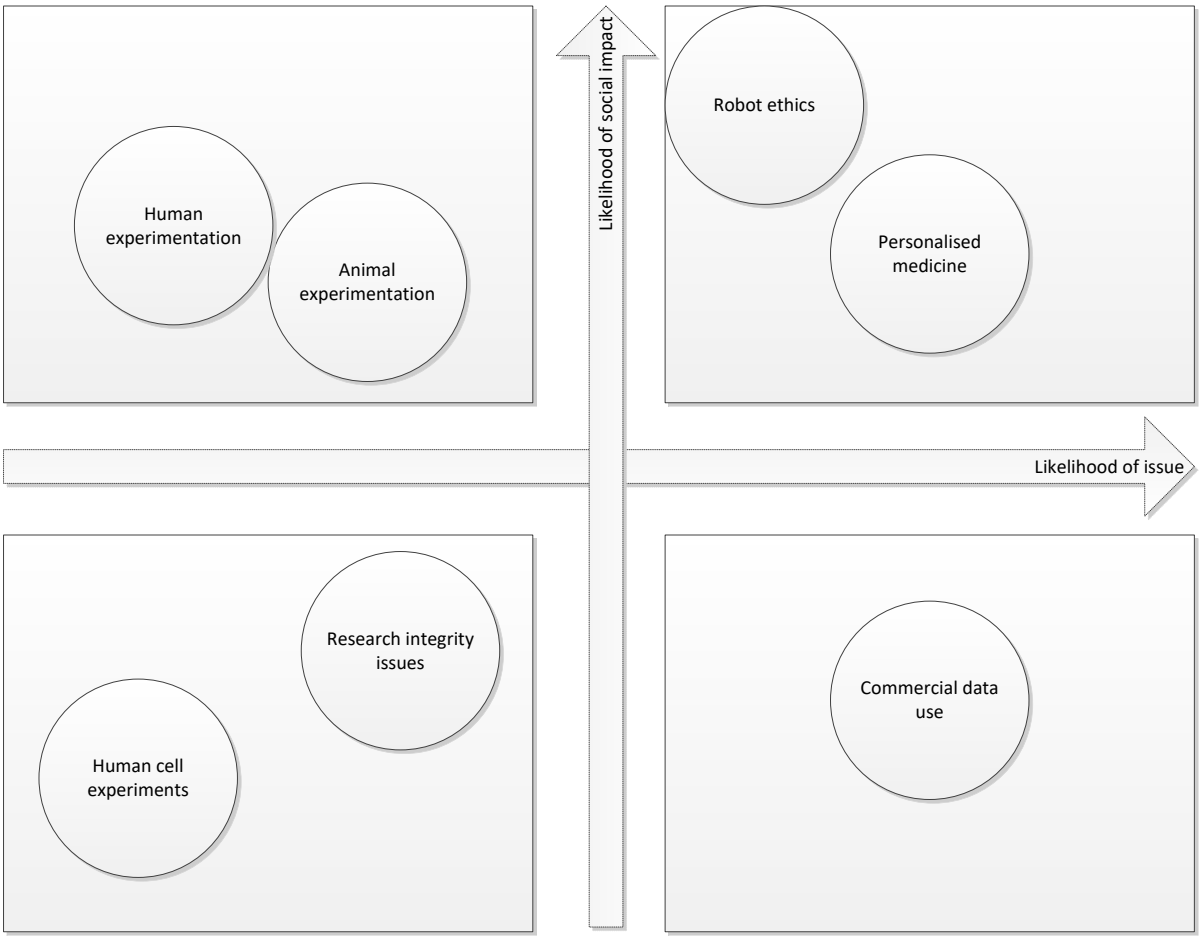

Figure 1 HBP Simplified ethics map illustration

For each item on the HBP Ethics Map a plan is developed specifying how it should be addressed. In this sense, the map is a management tool to help prioritise the use of limited EM resources. It is a useful tool that gives a 'tip of the iceberg' perspective on issues that are fleshed out by the rest of SP12 activity, as well as ongoing cross-HBP discussions.

Given the breadth of HBP ethical issues, the way in which they can be addressed varies widely. Some are subject to clearly established regulation and can be addressed by following the compliance policy described above. Others call for the development of specific policies and approaches to be developed by the HBP. Others again call for further research and may be subject to national or European legislation, standardisation, professional engagement and others.

Where the issue is highly specific and not subject to existing approaches or processes, a bespoke Ethical Issue Action Plan is proposed. An ethical action plan is a different format than an ethics map and so in conjunction they alleviate some of the problems a map might have on its own. The Ethics Map is an easy way to put all the issues in one field of vision so as to feel that they can be addressed. The action plan, however, gives the chance to be more detailed, to address the other ways the specific issue might be represented. And of course to start addressing it in the form of action. The Ethical Issue Action Plan outlines how the HBP decides to pursue the issue. A typical Ethical Issue Action Plan may have the following structure:

- Definition of the Issue
- Tasks Affected
- Proposed ways of addressing ethical issues
- Task-specific resolution
- Open questions
- Action list
- Review schedule
- Timeline
- References

Interviews

The first draft of the Ethical Issue Action Plan is normally produced by the Ethics Management team. It is discussed and agreed with research leads and managers in the relevant subproject. These interviews constitute an extremely useful way of keeping discussion central to the HBP EM processes; they ensure both that ethics management processes are well-informed concerning HBP activities, and that ethics and RRI are part of research rather than a mere *post hoc* add on. A dialogical method like this permits a lot of latitude for the kind of reflexivity hoped for by the EM group and SP12 more widely (Rose, Aicardi, & Reinsborough, 2015a). As such, these meetings can be seen as a good implementation of the rationale EM has developed. The agreed plan can be shared with and reviewed by the ethics and society subproject, and others with interests in the research.

Given the HBP is such a large and complex project that touches on numerous national legal and ethical requirements, already it can be seen how these four elements contribute to tackling the complexity. Self-assessment provides a baseline for EM to begin with. The Ethics Map lists all of these issues, as well as others emerging from other sources. Ethics Issue Action Plans outline for each of these how they are addressed, agreed in discussion with the relevant researchers and managers. Several other elements contribute to the overall ethics and RRI picture in the HBP, however. Some, such as the ethics registry which will be discussed next, focus on compliance matters. Others, such as the EAB, the rapporteur network and PoRE, are geared more toward the reflexive element of the ethics and RRI task.

Where specific ethical or legal issues arise that require approvals or permissions, these are collected in the HBP Ethics Registry. The registry is a resource to help manage the large amount of data on ethics issues. It is also paired with resources to help local research labs address their ethics issues, or to be sure that all their permissions are in place. Ultimately it is

the individual PIs that are accountable to their local ethics authorities, potentially in different jurisdictions with different regulations. The registry is a way to emphasise how in practice the theoretical idea of “everyone is responsible for ethics” is actually carried out and yet there is some meta-responsibility at play, resources are provided, discussion and dialogue, and advice are forthcoming. The ethics map is a visualisation of the issues in the registry. The registry itself connects tasks, ethics issues, action to be taken, researcher responsible, and a timeline in order that EM has an up to date and easily readable record of what is going on in ethics right across the HBP.

Ethics Registry

Those ethical issues that are subject to clear regulation and require ethical approval are handled via the process outlined above – self-assessment, interview etc. This is typically the case for established biomedical research, e.g. human subject research or animal research. It is also the case for other types of ethical issues as listed in the H2020 ethics self-assessment document. These documents are collected by the Ethics Compliance team and stored on a secure system, with end-to-end encryption, and with servers located in the EU (in order to abide by the highest data security measures).

The HBP Ethics Registry is summarised in an overview file which contains metadata of all ethics approvals that it contains. This data includes the research task in question, type of issue, details on the status, task leader, organisation, country and status of permissions. An essential piece of work connected with this map and the registry, is the development of standard operating procedures (SOPs) and the ethics action plans.

Standard Operating Procedures

SOPs are developed as general guidance on how to deal with particular issues in the HBP. Action plans for specific ethical issues were developed in collaboration with the affected scientists in order to give specific guidance on topics that fall outside of general guidance. These documents are linked to the HBP Ethics Map to indicate how the individual issues are to be addressed. Work on these documents is crucial because it allows for an open discussion across the different disciplines, with a view to ensuring that the issues are addressed in accordance with the overall aims of the project, and also with a view to broader societal concerns. This is therefore the step that allows for the harmonisation and alignment of different responsibilities, and the shaping of new ones where required. This clarifies to whom each of the roles within the HBP are responsible, making accountability transparent. Some key SOPs are described, with links available, below.

Given the conceptual background briefly described above, it is not the case that the registry and the map, and connected SOPs, are the entirety of ethics in the HBP. In order to constitute the sort of dynamic, discursive structures conceptualised, EM has also put in place other structures. Centrally, the rapporteur programme, ethics advisory board, and the PoRE mechanism provide dynamic and reflective capacity within HBP ethics.

Ethics rapporteurs and the EAB

The concept of an ethics rapporteur was originally proposed by a member of what is now the EAB. The objective of the Ethics Rapporteur Programme is to deepen understanding of

potential ethical and social implications of research and other work by the scientists and engineers in all the SPs, and to establish communication links that will help HBP achieve and maintain ethics and RRI goals. Rapporteurs are researchers (typically) who are very familiar with the work of their SP, and have been given a special brief of thinking ethically about that work. Rapporteurs are like points of contact for the rest of the ethics and RRI apparatus of the HBP, as well as spokespersons for those working in the SPs. Owing to their being implicated in SP research, they have knowledge that develops as does the research. This allows ethics and RRI to keep abreast of the dynamics side of research across the HBP. The work of rapporteurs enhances and formalises communication among the EAB, Ethics Management, and each subproject, as well as cross-cutting subprojects in the HBP.

The Ethics Rapporteur is a principal contact for the respective SP, communicating technical programme issues and ethical concerns, and interacting regularly with ethics management, each other in workshop settings, and the Ethics Advisory Board (EAB). This is a very useful feedback and reflexive function for HBP ethics. The idea is that together this collaboration will provide the subject expertise concerning the research undertaken in the SPs to inform ethics management of what is happening in the SPs. At the same time they can communicate, in particular compliance issues, to their SPs the thoughts and views of the EAB, of EM, and of SP12 more widely.

Ethics rapporteurs link their SP with the ethics EM and the EAB. The EAB, meanwhile, is a group of independent experts responsible for advising the HBP Science and Infrastructure Board (SIB) on specific ethical, regulatory, and social issues raised by research that is being undertaken or planned under the auspices of the Human Brain Project. They bring expertise from outside the HBP, which is of great value in a context of highly interlinking responsibilities.

In order to deepen the dialogical, discourse ethic-like rationale of EM in the HBP, broad collaboration between SP12 and the rest of the HBP ought to be a regular and consistent activity. To make this the case, contact between ethics rapporteurs, EAB members, SP managers and research leads, and EM. Typically, issues under discussion include not just perceived ethical challenges, but also remote concerns, as well as the very process of ethics management and RRI underway. This approach cements the investigative work of SP12, accumulating a valuable and timely knowledge basis for the ethics committees, while enabling more pragmatic examination of potential ethical, social and legal issues by other SPs.

Besides the independence of the EAB as an ‘outward-facing’ facet of the ethics and RRI provisions of the HBP, there is also a publicly accessible mechanism through which ethics issues may be raised. This is an important part of an RRI provision in particular as it sets up a channel of communication with the public at large, recalling the idea that all citizens are research stakeholders (Felt et al., 2007).

Registration of new Ethical Issues

The PoRE (the Point of Registration of Ethical Issues) is a tool for the use of both those inside and outside of the HBP. It is a mechanism that permits the raising of ethics questions about any aspect of the HBP. This openness provides a channel that can feed into ethics thinking in the HBP on an issue by issue basis, not necessarily connected to the framings imported to the work by those inside the various SPs. As well as this, the PoRE facility provides a means

through which known ethics issues can be logged comprehensively. By using PoRE as a kind of ethics indexing tool, an up to date record of ethics actions can be maintained.

Because it has a public face (www.hbp-pore.eu), PoRE can be an input to the overall ethics and RRI provisions of the HBP that does not mischaracterise 'the public' in some way. Instead, the views, questions, perceptions, and concerns of any citizen can be logged and enter the processes above described. As a tool, this is an effort to 'bring science closer to society', which is a grand aim of RRI in general.

Diagram of ethics processes in the HBP

The below diagram demonstrates the complexity of the HBP ethics processes, but also hopefully displays the completeness of the mechanisms put in place. It should be noted that, as an illustration, this is not necessarily complete, nor self-explanatory. It is perhaps best thought of as a device to aid a fuller understanding of HBP ethics gained in reading this and later documents, and should be viewed with the foregoing discussions borne in mind.

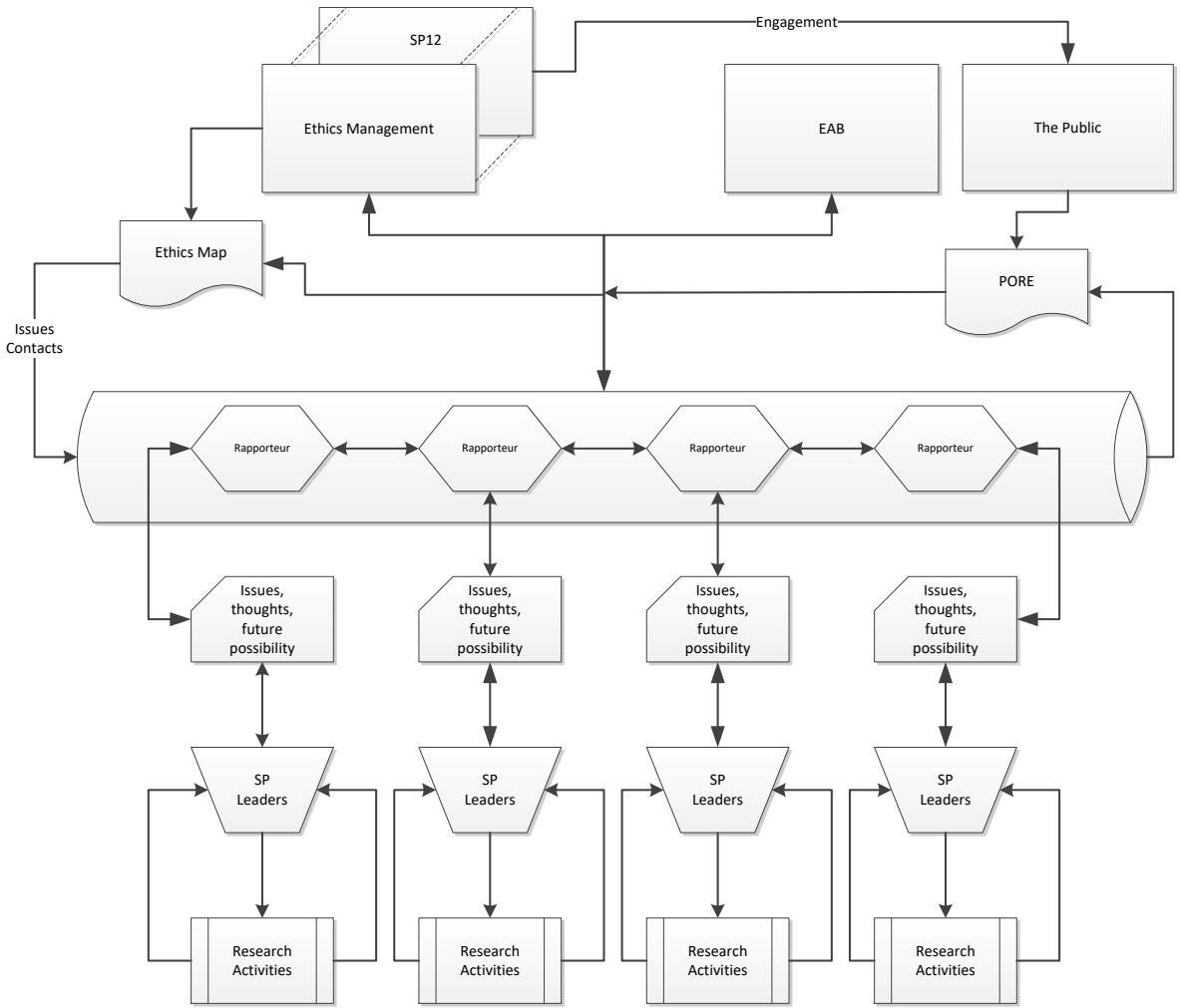

Figure 2 Depiction of ethics management processes

The challenge for the Society & Ethics sub-project

Research is ongoing within the Society & Ethics Sub-project of the HBP (SP12) to examine existing issues relevant to ethics and RRI. This research aims to identify possible future issues, and to reflect upon the processes at work in the HBP. Maintaining researcher awareness across the HBP is an important part of implementing SP12 research findings within the complexity of broader HBP activity. Work from SP12 has indeed already filtered through to the researchers of the HBP, and has stimulated modes of thought across a variety of SPs. There remains the challenge of maintaining this in a clear and tangible way.

The EPSRC's 'anticipate, reflect, engage and act' (AREA) framework used broadly in SP12's work serves as a way to organise the SP's efforts. The challenge just described comes in the final 'A'. Whilst it is clear that anticipation, reflection, and engagement take place, it is challenging to ensure that this manifests in *action*. For a successful RRI approach, a strategy is needed that will 'close the loop' here, highlighting the coherence of SP12 research and its implementation throughout the HBP. There are likely many ways to conceptualise and explain the efforts in this area. One important such way to address the open loop challenge will centre on the concept of researcher awareness, and include at least four components:

a) action plans
b) workshops
c) leveraging the ethics rapporteur programme
d) using existing ethics management tools

Researcher awareness is a workpackage in SP12. Its work can synthesise action plans from original research and from insights gained within the working of the HBP as a whole. These action plans can be tested in workshop environments. Workshops have proven successful means of engagement between SP12 and the rest of the HBP during the opening phases of the project. The action plans can both motivate workshop topics, as well as be refined in those same workshops.

Once clear action plans are devised, these can be disseminated internally among (at least) the existing ethics rapporteurs. In providing this group with action plans based in solid and tested research, researcher awareness will be showing the outcomes of research, and at the same time capacitating the rapporteur group – providing the means to frame, and re-frame existing approaches to research. Especially in a general context of RRI this is highly valuable.

Lastly, where action plans shed light on essential, perhaps overlooked, unanticipated, or new aspects of HBP work, they can be translated into project norms through the use of existing ethics management apparatus (e.g. ethics compliance; ethics surveys; standard operating procedures).

Utilising resources from SP12 research, such as findings in neuroethics, foresight lab work, and ethics management structures, HBP-wide efforts can take place to increase the awareness of ethics throughout the HBP. This is important so that reflective ethical research can take place. Ethics Management plays a key role in clarifying and addressing these issues and reporting on them.

The experience so far

The structure and processes of ethics management will remain open to further development. They are, however, now generally stable and established. The focus is now on fine-tuning them and ensuring they work as intended. This is also an opportunity to do self-reflexive and empirical/experiential study of putting plans into process, field testing them and recalibrating systems where required or desired.

Achievements

The main challenge for the EM has been to become second nature for researchers throughout the project. To a satisfying degree, this has been the case. The idea of ethics as a frustrating tick-box exercise, designed to thwart free research, has been overwhelmingly overtaken by a generally quite well-disposed attitude. Rather than feeling frustrated, using the EM apparatus, HBP researchers seem largely happy to discuss ethics issues and the processes of ethics management themselves across a variety of contexts. This experience grounds good questions for ongoing research within the HBP consortium and fuels an increasing ease with interdisciplinarity that cannot be taken for granted among large and diverse groups of researchers.

Concerning the overall infrastructure, questions of data governance became pressing in the run-up to the platform launch in March 2016. During this time, the ethics manager prompted the instigation of a data protection working group whose explicit remit was to tackle issues in just these areas. The key outcome of these activities was the terms and conditions of the Collaboratory, a central part of the HBP. While this is an important document clarifying some of the data governance issues it is also clear that data governance is a question of highest importance to the HBP overall. The provisional data governance working group has therefore proposed an agenda for further work to the coordinator and the SIB. Relatedly, SP12 and EAB have authored a shared Opinion on Data Protection. This Opinion will be further developed, and then form part of a researcher awareness exercise.

The rapporteur programme has enjoyed a good uptake especially following meetings in Paris' Institut Pasteur during which a rapporteur workshop was held. The rapporteur program is a good example of distributed responsibility within an overall framework of responsibility, demonstrating the concept of meta-responsibility in practice. The rapporteur network has been well explained throughout the project, and the rapporteurs have played a helpful role in ongoing discussions and debates – notably on dual use issues (a focus of the Paris rapporteur workshop). Organisational change is a challenge for the rapporteur programme as staff change roles within their institutions. Future work will be needed to maintain the links and to engage these researchers in the ethical issues that go beyond "compliance" about which they expressed considerable interest.

Challenges remaining

In a general sense, the very notion of RRI is open to critique. Some of this critique can be rather fundamental (de Saille & Medvecky, 2016) but which is nonetheless aimed at increasing discussion in the area of responsible innovation. The challenge for the HBP is thus how to include RRI as an ongoing research area, within an ongoing research project which is itself

incredibly complicated and diverse. This requires very clear communication strategies and practices.

In the first foresight report from SP12's Foresight Lab (Rose, Aicardi, & Reinsborough, 2015b), this has been approached. This report emphasises the integrative aspect of RRI, getting people to talk to each other from different locations within the research and stakeholder system to 'join up the dots' and motivate action. The AREA framework mentioned above might be revised to *AREA plus I*. This responds to the sense in which A, R, and E cannot be separated but must be brought together in A. For presentation purposes most people keep them separate, but as HBP work has found this is artificial. Workpackages could all accomplish tasks without bringing together cross-flagship work and communicating, acting together.

Ethics management in a context of RRI deals mainly with the distribution and monitoring of responsibilities. This might be seen as the sharp end of dealing with RRI, but not necessarily as being reflective enough a space in which to mull the content of RRI. While it is the case that those working in ethics management have research profiles and experience in areas of RRI, the challenge remains nonetheless to integrates the practical with the reflective construction of RRI within the HBP. This is a particular challenge for SP12, but of course it ought to be a challenge felt across the HBP as a whole. Moreover, the work of the EM team is extremely labour-intensive. This is a cost associated with the benefit of flexibility and openness. Further testing, streamlining and normalising of the activities of EM in the HBP could serve to mitigate this.

At this point there is no formal collaboration between the HBP and other similar ventures such as the US BRAIN initiative. During the meeting of the EAB and Ethics Rapporteurs in March 2016 a representative of the neuroethics committee of the US BRAIN initiative was present and presented their work. It remains a challenge as to if and how the HBP and other, non-European projects might interact. The US position concerning dual use is fundamentally different from the EU / HBP one for instance. Issues exist where data, especially personal data, would be shared across borders. Nevertheless, where such challenges could be met, more collaboration could be a positive goal.

Recommendations from the experience

A fundamental trust in the research integrity of local PIs and SP leaders allows for ethics management to approach ethics throughout the HBP with candour. Technical solutions to compliance management have permitted cooperation across SPs, as well as providing mechanisms that allow SPs to see what is required and how to comply. The network of rapporteurs, and PoRE have allowed for ethics management to be a two way street, mitigating the finitude of our own ethics imaginations. This has provided robust ethics infrastructure, as well as reflective ethical awareness across the project as a whole. These mechanisms are not merely theoretical, but have been utilised to produce HBP-wide discussions on ethics; compliance interviews and cooperation leading to a robust ethics registry; PoRE submissions have arrived; a record of SP-leader, manager, and rapporteur ethics discourse.

At present the RRI discourse tends to shy away from the question of *who* is responsible for RRI. The rationale of taking on a meta-responsibility approach permits agility in approaching ethics and RRI, and goes beyond this limitation. We suggest that the quality of the discourses

on RRI and associated topics are the loci of responsibility. These discourses are built up from the resources put in place by SP12, including the research and infrastructural components; conceptual research, empirical research, public engagement, and the parts of EM like self-assessment, PI interviews, ethics registry, EAB, rapporteurs combine to provide the means for these discourses to proceed. I Using all of this, those who take part in and contribute to the discourse are charged with keeping them of high quality. This means involving the correct people, ensuring good questions are asked, pursued, and so on. Where the discourses fail, or fall short, action is needed and the shared responsibility of those who have contributed is activated. The propositions, the reasons, the concepts put into play are up for reinforcement, revision, rejection in the case where problems arise. This is, at least, a form of mutual responsiveness, or co-responsibility. In being practicable, it is a way to promote RRI. Mutual responsiveness facilitates communication, trust, and resource distribution, so that responsibility for ethical concerns can be distributed to individual actors for specific issues. But it also shares in terms of support for individuals and communicative dialogue, in some cases collective decision making about big issues, and a general sense that responsibility is successfully distributed in the overall research systems of the HBP.

Through all of the resources just mentioned, researchers across the HBP can express, reflect upon, carry out, and advance their HBP research agendas. In providing cross-HBP facilities for discourse, and the idea of meta-responsibility, this mutual responsiveness grounds a strong, adaptive, ethics and RRI *modus operandi* for this complex flagship research project.

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