



FAQ - Ethics Management in the HBP

1 - Why should I care about ethics management in the HBP?

The Human Brain Project generates intense public curiosity as well as widespread scientific interest owing to its activities and promise. Ethics management provides a practical way of embedding responsibility for overseeing research and paying attention to ethical and social implications of this world-leading project to greatly expand knowledge about the human brain.

While the open and public nature of modern science is to be prized and defended, there are ample historical examples that its own internal procedures are not sufficient to prevent ethically unjustifiable means of gaining new knowledge nor adequate to foresee nor concurrently evaluate the risks of harm and promise of benefits from research applications. Science, like all human endeavors, is therefore subject to ethical scrutiny, social debate, and public input about the pursuit and use of new knowledge. The ethics and society component of the HBP is responsible—through its ethics manager and steering committee, and through its independent Ethics Advisory Board-- for oversight of research protocols, for linking with scientists in HBP work packages to anticipate and investigate ethical concerns, and for engaging with the public regarding the work of the Human Brain Project. Ethical management is responsible for these aspects of HBP such that the ethical quality of the HBP is reflected in all aspects of the conduct of research.

2 - Who is responsible for ethics in the HBP?

You are! All members of the HBP play a role in ensuring that ethical standards are defined and upheld. Undertaking research and innovation responsibly is a shared responsibility of all groups and individuals.



3 - How is ethics managed?

The HBP has a subproject on ethics and society (SP12) which provides research and organisational support to the overall project to help identify social and ethical issues and address them appropriately. Ethics management is one work package within SP12, led by the Ethics Manager. The ethics management WP deals with the central administrative and organisational aspects related to ethics. It works closely with the research WPs in the SP and with members of all other SPs. It remains the responsibility of the PIs to obtain the appropriate authorisations or approvals from the relevant authorities before engaging in activities with ethical dimensions, (see FAQ #9).

4 - What are the ethical issues in the HBP?

There are numerous ethical issues which have been identified by SP12. These range from traditional 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. The ethics management WP collects all of these issues and tracks the way they are addressed. Below is a graphical representation of current (August 2015) ethical issues in the HBP, the ethics map.



HBP Ethics Map

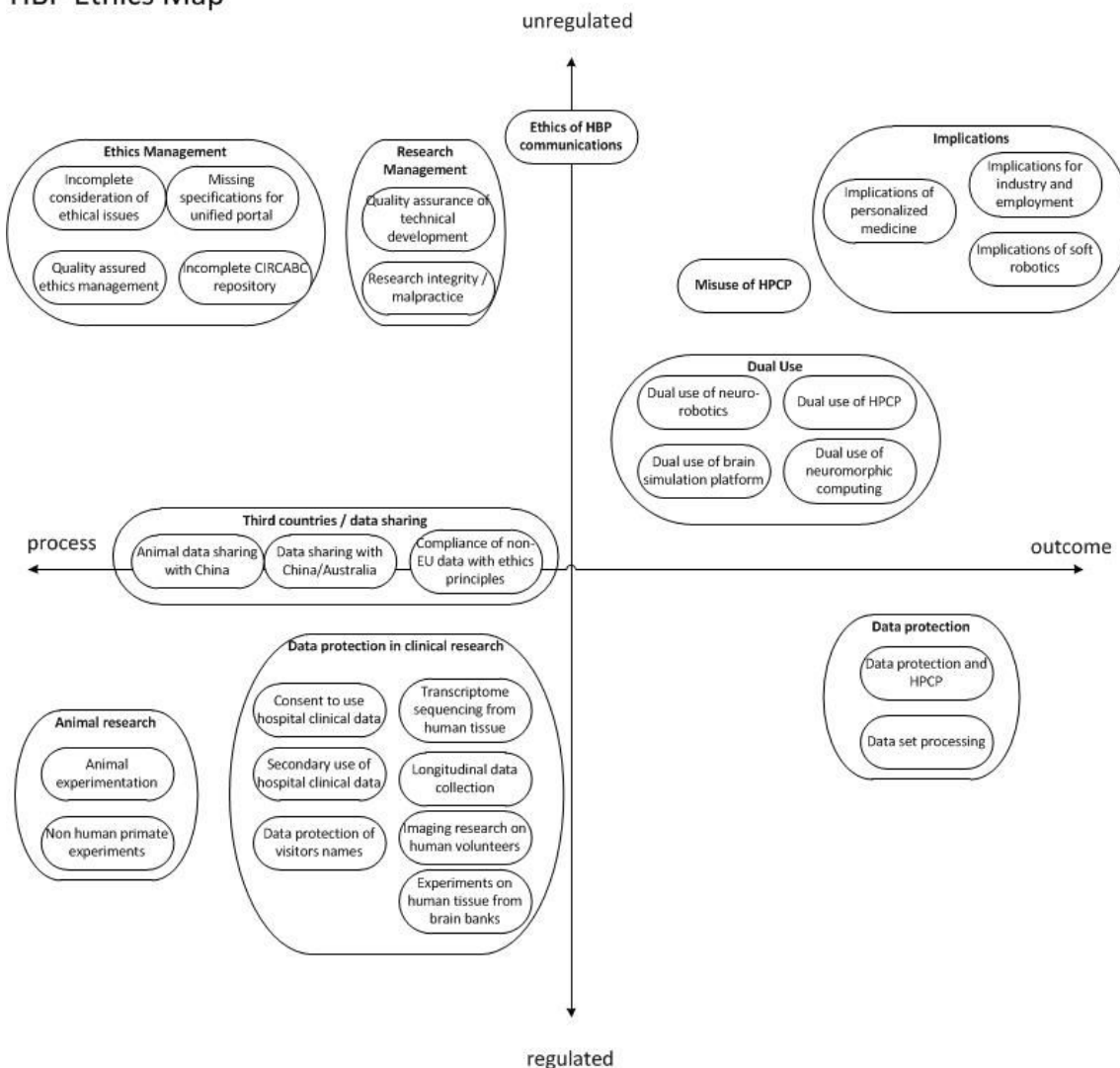


Figure 1: Graphical representation of ethical issues in the HBP

This figure shows the ethical issues as identified by the ethics review in January 2015, ordered by the degree to which they are subject to formal regulation and their location on the spectrum between research process and outcome of research. The larger clusters are attempts to group ethical issues to help find shared solutions.



5 - I have concerns about an ethical or social aspect of the HBP. What should I do?

One activity of ethics management is the Point of Registration (PORE). Anybody who would like to raise a concern (HBP member or external) can do this here:

www.hbp-pore.eu

Each submission to the PORE registry will be redirected within 2 working days to the most appropriate HBP entity: the PORE Registrar prepares a simple document for presentation to the Ethics Manager, the SP12 Steering Committee, and / or the Ethics Advisory Board, as appropriate. The outcomes of every PORE submission will be communicated to the person who made the submission and other relevant stakeholders.

6 - Who oversees the way the HBP deals with ethics?

The members of SP12, including all members of the ethics management WP, are HBP members. Their work is assessed by the external Ethics Advisory Board. In addition the HBP is subject to regular technical and ethics reviews as well as ethics audits by the EC where processes and outcomes of ethics management are assessed.

7 - What is the Ethics Advisory Board?

The Ethics Advisory Board is a group of independent experts. It is responsible for advising the HBP Board of Directors (BoD) on specific ethical, regulatory, and social issues raised by research that is being undertaken or planned under the auspices of the Human Brain Project. Details about the EAB can be found in the EAB SOP.

8 - What is an Ethics Rapporteur?

Ethics rapporteurs are researchers who link their SP with the ethics management WP and the EAB. The idea is that they 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.

Each SP should have at least one nominated rapporteur. If you want to talk about the ethical and social issues in your SP, then your rapporteur should be a first port of call before using the PORE.

9 - Do I need ethics approval?

There are a number of activities undertaken in the HBP that require formal ethics approval. The European Commission has provided guidance for [H2020 ethical self assessment](#) that gives an overview of these issues and how they are to be addressed. Very briefly, the most important ones are:

- Research on humans
- Human cells/tissues
- Personal data
- Research on animals
- Research involving third countries
- Dual use and misuse

If your research involves any of these you are likely to be required to gain ethics approval. If in doubt, please contact the ethics management team.

Further information on ethics approval and compliance is given in the SOP on ethics compliance management.

10 - I have a good idea of how to deal with ethics. What should I do?

The principles and processes described here are an attempt to cover all ethical and social issues in the HBP. We realise they may not be perfect and there may be better ways of doing things. If you have a suggestion or proposal, we would be delighted to hear from you and improve the way we do things.

Please check below for how to contact us. We would love to discuss ways to improve ethics management with anybody from within the HBP and also with external stakeholders.



11 - Does the HBP have an Ethics Ombudsperson?

The HBP will have an ombudsperson, i.e. an independent point of contact to raise issues anonymously. The role of the Ombudsperson will be integrated into the ethics management activities over the course of the period from April 2016 to March 2018.

At present the [PORE](#) system can be used to make anonymous submissions. Furthermore, the EAB chairs can be approached by anyone wishing to have a confidential communication about ethics in the HBP. They can contact them as follows:

Henrik Walter: henrik.walter@charite.de

Karin Blumer: karin.blumer@novartis.com

12 - Where can I find more information?

The ethics management work package has a dedicated page on the HBP website:

<https://www.humanbrainproject.eu/ethics-management>

In addition you can contact us directly:

- Bernd Carsten Stahl (HBP ethics manager): bstahl@dmu.ac.uk, tel: +44 116 207 8252
- Mark Shaw (team member of the ethics management team): mshaw@dmu.ac.uk, tel: +44 116 207 8940
- Stephen Rainey (team member of the ethics management team): stephen.rainey@dmu.ac.uk

13 - Members of SP12, EAB and Ethics Rapporteurs

There are a number of people interested in the ethical, social, conceptual and regulatory questions of the HBP. The picture below shows the participants of a joint meeting of SP12, the Ethics Advisory Board and the Ethics Rapporteurs in June 2015 in Paris.



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