

SOP Title:	Ethics Advisory Board
Partner Responsible:	Ethics Manager, EAB members
SP / WP / Task Involved:	SP12, EAB
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Abstract:	SOP defines the role and processes of the Ethics Advisory Board
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Document Status

Date	Comments
	Initial draft
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1 Function

The Ethics Advisory Board (EAB) is an independent body that advises the HBP Board of Directors (BoD) on specific ethical, regulatory, social and philosophical issues raised by research that is being undertaken or planned under the auspices of the Human Brain Project.

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 will advise on its own initiative as well as upon requests made by researchers, or other members of HBP, about specific ethical, regulatory, and social issues arising from their research undertaken within the HBP or by collaborators.

2 Implementation

2.1 Membership

Regular members who comprise the EAB are unpaid experts who have been chosen for their knowledge in a specific area relevant to the HBP. Membership of the EAB is determined by competence, geographical and gender balance. The EAB particularly values diverse perspectives.

2.1.1 Appointment of New Members

New members will be proposed by the EAB when expertise on the committee does not match the need for core competency, or when the number of members falls below 13.

Members of the EAB will be appointed for a renewable term of three years. The first term of office for members of the EAB will officially start at the HBP Summit in September 2015.

When new members are appointed, their three year term begins at the time of appointment.

2.1.2 End of membership

EAB members who come to the end of their tenure can ask to remain on the Board. The EAB can decide to extend their term with a simple majority vote. Membership will also end if members participate less than 3 times in the regular meetings over a period of 2 years.

2.1.3 Declaration of interests, recusal

EAB members have to declare potential conflicts of interest. Where issues are discussed that may involve a conflict of interest, the affected member shall recuse herself / himself from the discussion.

Conflicts of interest can be reported in oral or written form and should be noted in the minutes of the relevant meeting.

2.1.4 Ex Officio Members

Ex officio members from SP12 attend meetings of the EAB as non-voting participants.

2.2 Leadership and Internal Decisions of the EAB

2.2.1 Chairs of the EAB

The EAB has a Chair and a Vice Chair. The EAB will elect its chairs from among its members. The tenure of the chairs is two years, renewable for a further 2 years. The Chairs have the following roles:

- Representation of the EAB to the HBP and external bodies
- Organising representation of the EAB at annual and ethics reviews
- Organising the working structure of the EAB (e.g. thematic groups, core group)
- Communicating relevant information to the EAB members
- Working with the Ethics Manager and the EAB Secretariat in planning and executing meetings, agendas etc.
- Ensuring quality assurance for EAB opinions or other official statements

2.2.2 Attendance

Meetings of the EAB will be attended by

- EAB Chairs and members
- ex Officio members
- Representatives of the EAB Secretariat

- SP12 directors or members (where requested)
- Further invited participants where required

2.2.3 Internal Decisions

Decisions of the EAB are made by consensus, wherever possible. Where no consensus can be reached and a decision has to be made, the members of the EAB can make majority decisions. Each member has one vote which can be transferred to a proxy.

The EAB is quorate if at least $\frac{2}{3}$ of its members are present or can vote by proxy. If a meeting of the EAB is not quorate, votes can be held electronically after the meeting.

Votes only have binding force if they were announced in the agenda or through alternative means at least one week prior to the meeting. Where it becomes clear during a meeting that a vote is required, the vote can be held electronically after the meeting. This should normally happen within two weeks of the meeting.

Where decisions have to be made and no meeting is planned, the Chairs can call for a vote using appropriate electronic or other means one week after the decision to vote.

2.3 Working Principles

2.3.1 Communication

The EAB uses an electronic mailing list to communicate all information relevant to all of its members. All members should be kept up to date electronically and should receive the HBP newsletter.

EAB Chairs will have a teleconference with Ethics Manager and Secretariat at least on a monthly basis.

2.3.2 Meetings

The EAB will have three meetings per year. One of these meetings will be co-located with the HBP summit.

Meetings are scheduled by the Secretariat in consultation with the Chairs.

The agenda of the meeting will be shared with EAB members at least two weeks prior to the meeting.

2.3.3 Confidentiality of meeting material

Although EAB members are subject to a confidentiality agreement with the HBP, the guiding principle is transparency.

2.4 Collaboration with the HBP

2.4.1 Relationship with the HBP

Under authority delegated by the HBP Board of Directors, and coordinated with the Ethics Manager, the EAB may communicate with individual researchers, and should enjoy open access to communication about the project.

The EAB's access to SP12 scientific and engagement data and results, and other information and resources, is managed by the SP12 Ethics Manager. The EAB has the right to access all material of the HBP that is available on EMDESK. In anticipation of its deliberations, EAB may advise that SP12 scientific attention be brought to specific areas of special interest, which may call upon scientific research, public engagement or philosophical inquiry. The Ethics Manager holds a subcontracting budget that can be used to acquire additional expertise required by the EAB in a short timeframe.

The collaboration between the EAB and SP12 is facilitated by the Ethics Manager, who normally coordinates communications regarding requests of the EAB. However, the EAB is privileged to communicate with the Board of Directors directly.

The EAB may recommend to the BoD to review, monitor or audit specific aspects of the research. Such a recommendation should be made in writing and will normally communicated to the BoD via the Ethics Manager. The BoD commits itself to responding to such a recommendation in writing within 4 weeks.

2.4.2 Relationship with rapporteurs

The Ethics Manager will oversee that each subproject in the HBP appoints at least one ethics rapporteur (ER) to liaise that researcher's own SP and the EAB.

2.4.3 EAB's role in compliance management

The EAB will have full access to all judgments by authoritative bodies responsible for vetting research, which may pertain to any part of the HBP, typically via the Compliance Management process.

Where ethics approval and compliance has been acquired outside of the jurisdiction of European Member States or where no ethics approval has been gained but the research has been identified by the Compliance process as requiring ethics approval, the EAB can be asked to provide advice to the researchers in charge of the research activity.

The request for advice is normally raised by a member of the Ethics Management WP and forwarded to the Chair of the EAB. The aim of this process is to help the PI in question to

gain ethics approval from a competent local or national authority. The PI remains responsible for gaining ethics approval and implementing it.

Details of the ethics compliance process is given in the [Compliance Management SOP](#).

2.4.4 Review of SOPs and Ethics Management Processes

The Ethics Manager will coordinate the planning and implementation of Standard Operating Procedures.

Included as SOPs are written recommendations that modify, stop, or hold in abeyance research work.

2.5 EAB Opinions

Subject to confidentiality agreements, the EAB may disseminate opinions and seek to motivate opinion through publishing summaries of its deliberations, opinions and recommendations. All EAB opinions will be made available on the EAB webpage, which is part of the SP12 website.

Where the EAB disagrees on specific issues, opinions can contain majority and minority views.

EAB Opinions are forwarded to the BoD for acknowledgement.

2.6 Publications by EAB members

EAB members as independent subject experts in the various fields of the HBP may publish in this context. Their publications can serve as documentation of the underlying arguments for particular decisions.

Where those publications express personal opinions that are not supported by an official EAB Opinion but could be interpreted as originating from the HBP, EAB members should make it clear that they are writing in a personal capacity.

3 Review schedule

The SOP will be reviewed on a yearly basis by the EAB.

4 Appendix A: List of EAB Members

[Please click on this link to see the overview of EAB members.](#)