

SOP Title:	Ethics Advisory Board
Partner Responsible:	Ethics Director, EAB members
SP / WP / Task Involved:	SP12, EAB
Current status	Active

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Editor:	Bernd Stahl	

Abstract:	SOP defines the role and processes of the Ethics Advisory Board
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Document Status

Date	Comments
	Initial draft
15.06.2015	Approval by EAB
03.09.2015	Approval by SP12 Steering Committee
05.10.2015	Approval by BoD
13.10.2016	Annual Review of the Document by EAB
04.06.2018	Review, Update and Approval of the Document by EAB
27.09.2019	Review, Update and Approval of the Document by EAB

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1 Function

The Ethics Advisory Board (EAB) is an independent body that advises the HBP Science and Infrastructure Board (SIB) and Directorate (DIR) 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 Ethics Director facilitates access and communication with the HBP as a whole.

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.

Once established, the EAB will also work closely with the Ombudsperson of the HBP who will be invited to join the EAB meetings on a regular basis.

2 Implementation

2.1 Membership

Regular members who comprise the EAB are 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.

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.

The EAB appoints new members on the basis of their competency in the relevant subject. The EAB shall document its choice(s) of the new member(s) and state the basis for selection in each case. This statement is forwarded to SIB and DIR for comment. When the new appointment has been discussed in SIB and DIR and comments have been taken into account the EAB forwards the proposal of a new appointment to the Stakeholder Board for ratification. The term of office of the new member commences at the first EAB meeting after ratification.

2.1.2 End of Membership

EAB members who come to the end of their tenure can remain on the Board. A formal letter will be sent to each relevant member approximately one month before their renewal period is due. Each member will be asked to confirm if they are interested (or not) in continuing on in the EAB. The EAB can decide to extend the term of interested members with a simple majority vote.

Membership will automatically end if a member has missed three consecutive meetings.

Membership may also end upon individual requests, e.g., retirement or for personal reasons.

2.1.3 Declaration of Interests, Recusal

EAB members have to declare potential conflicts of interest, via a submission to the registry of interests (see SOP on Conflict of Interests). 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.

2.2 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 two 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 Director and the Ethics Support team 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
- HBP Ethics Director
- EAB Support coordinator
- Other representatives of the Ethics Support team (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 minutes of the SIB and DIR meetings.

2.3.2 Meetings

The EAB will have two physical meetings per year. One of these meetings will be co-located with the HBP Summit where feasible. Dates for physical meetings will be determined as early as possible.

There will be one or more teleconferences between physical meetings as needed. The EAB Chairs will additionally have teleconferences with the Ethics Director on an “as needed basis”.

Meetings are scheduled with the Ethics Director in consultation with the Chairs. The agenda of each meeting will be shared with EAB members at least one week 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 Remuneration Allowance

The members of the EAB will receive a lump-sum remuneration allowance and reimbursement of their travel expenses.

2.5 Collaboration with the HBP

2.5.1 Relationship with the HBP

Under authority delegated by the SIB, and coordinated with the Ethics Director, the EAB may communicate with individual researchers, and should enjoy open access to communication about the project.

The collaboration between the EAB with the DIR and SIB is facilitated by the Ethics Director, who normally coordinates communications regarding requests of the EAB. However, the EAB is privileged to communicate with these bodies directly.

The EAB's access to HBP scientific and engagement data and results, and other information and resources, is managed by the Ethics Director. The EAB has the right to access all material of the HBP that is available on EMDESK and in relevant repositories, such as Collabs. In anticipation of its deliberations, EAB may advise that HBP scientific attention be brought to specific areas of special interest, which may call upon scientific research, public engagement or philosophical inquiry.

The Ethics Director holds a subcontracting budget that can be used to acquire additional expertise required by the EAB in a short timeframe.

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

2.5.2 Relationship with the Science and Infrastructure Advisory Board (SIAB)

From time to time SIAB and EAB will have common meetings. The EAB is invited to each SIAB meeting.

2.5.3 Relationship with Rapporteurs

The Ethics Director will oversee that each part of the project in the HBP appoints at least one Ethics Rapporteur (ER) to liaise that researcher's own part of the project and the EAB.

2.5.3 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 Support team 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](#).

2.5.4 Review of SOPs and Ethics Support Processes

The Ethics Director 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.

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

EAB opinions are forwarded to the SIB and / or DIR for acknowledgement. All EAB opinions will be made available on the EAB webpage, which is part of the HBP website.

2.7 Publications by EAB Members

EAB members as independent 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 a publication implies that it is the opinion of the EAB, or refers to certain SPs, respective members should be consulted and invited to review before submission.

Where a publication expresses personal opinions that is 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.

Further details of publication procedures can be found here: [EAB Publication Etiquette](#).

3 Review Schedule

This SOP will be reviewed on a regular basis by the EAB.

4 Appendix A: Further Information on EAB Members

Current overview of EAB Members (November 2019):

- Berit Bringedal, LEFO - Institute for Studies of the Medical Profession, Oslo, Norway
- Markus Christen, Digital Science Initiative, University Of Zurich, Switzerland
- Josep Domingo-Ferrer, Department of Computer Engineering and Mathematics, Universitat Rovira i Virgili, Tarragona, Catalonia
- Hannah Maslen, Uehiro Centre For Practical Ethics University Of Oxford, UK
- Miguel Medina, CIBERNED - Center For Networked Biomedical Research in Neurodegenerative Diseases, Madrid, Spain
- Christine Mitchell, Center for Bioethics, Harvard Medical School, USA
- Sven Nyholm, Department of Philosophy, Utrecht University, Netherlands
- Melita Šalković-Petrišić, Department Of Pharmacology and Croatian Institute for Brain Research, School Of Medicine, University Of Zagreb, Croatia
- Vicenç Torra, Department of Computer Science, Maynooth University Hamilton Institute, Ireland
- Blaise Yvert, BrainTech Laboratory, INSERM and Univ Grenoble Alpes, France

[Contact details and short profiles of EAB Members on HBP Website](#)