Governance Handbook (D11.1.1 – SGA2)

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Description in GA:	DIR handbook with procedures to follow regarding internal management, interactions with PCO, with SP Leaders and with Advisory Boards. (T11.1.2)		
Abstract:	This handbook provides an overview and guidance on the structure of the HBP governance, the workflow of the decision-making processes, and interactions between the different HBP Governing Bodies, HBP Advisory Boards and specific connected roles in the HBP.		
Keywords:	Governance, Stakeholder Board, Steering Committee of the Stakeholder Board, Directorate, Science and Infrastructure Board, Ethics Advisory Board, Science Advisory Board, Clinical Advisory Board, Project Coordination Office		
Target Users/Readers:	Members of governing bodies and advisory boards, governance support, Consortium		

Note to readers: this document contains references to confidential annexes which are not shown.

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1. Purpose and Limitations

This handbook aims to provide an overview of and guidance on the structure of HBP governance, the workflow of its decision-making processes, and interactions between the different HBP Governing Bodies. The handbook is based on current practices and on the governance sections of the HBP Framework Partnership Agreement (FPA, EC Project No. 650003) and the HBP Consortium Agreement (CA), but does not replace those agreements, which remain the ultimate authorities on HBP governance. Additionally, there are several terms of references (ToRs) and standard operating procedures (SOPs), which set out principles governing the functioning of these bodies.

2. Context and Overall Governance Structure

The Human Brain Project (HBP) is a FET Flagship Project, a large-scale, long-term EU research initiative with a planned duration of ten years, involving more than one hundred Partners. It is currently coordinated by the Ecole Polytechnique Fédérale de Lausanne (EPFL) in Switzerland. Given the size of the Project and its multidisciplinary nature, it is currently divided into 12 Subprojects (SP).

The HBP started off with a Ramp-Up Phase, funded by the European Framework Program 7 (FP7), which ended in April 2016. The Project then entered its operational phase (2016-2023) under Horizon 2020 rules (H2020), in which it is governed by a Framework Partnership Agreement (FPA). The FPA covers multiple Specific Grant Agreements (SGAs), each of 2-3 years' duration, through which the Project receives funding from the European Commission.

Under the Ramp-Up Phase, the core Governing Bodies comprised:

- A General Assembly, with one Member per HBP Partner organisation;
- A Board of Directors with 12 Members; and
- An Executive Committee, with 3 Members.

During the Ramp-Up Phase, the Project underwent a mediation process. The resulting report stipulated that the then-Board of Directors of the HBP and the Executive Committee should be replaced with a new governance structure, to ensure a better separation of powers. The new governance structure saw the creation of the following bodies: the Stakeholder Board (SB), the Steering Committee of the SB (SCSB), the Directorate (DIR), and the Science and Infrastructure Board (SIB). These have been active since June 2016, following a decision by the former General Assembly.

Advisory bodies have also been set up for certain specific fields, such as science, clinical topics and ethics, to provide guidance and support to the Project in their respective fields.

The Project Coordination Office (PCO) is in charge of coordinating the implementation of the Project, in particular coordination of Proposal-drafting, Project Reports and Deliverables, communication, and development of HBP-specific IT tools for managing the Project, such as the HBP Collaboratory, PLA and PLUS.

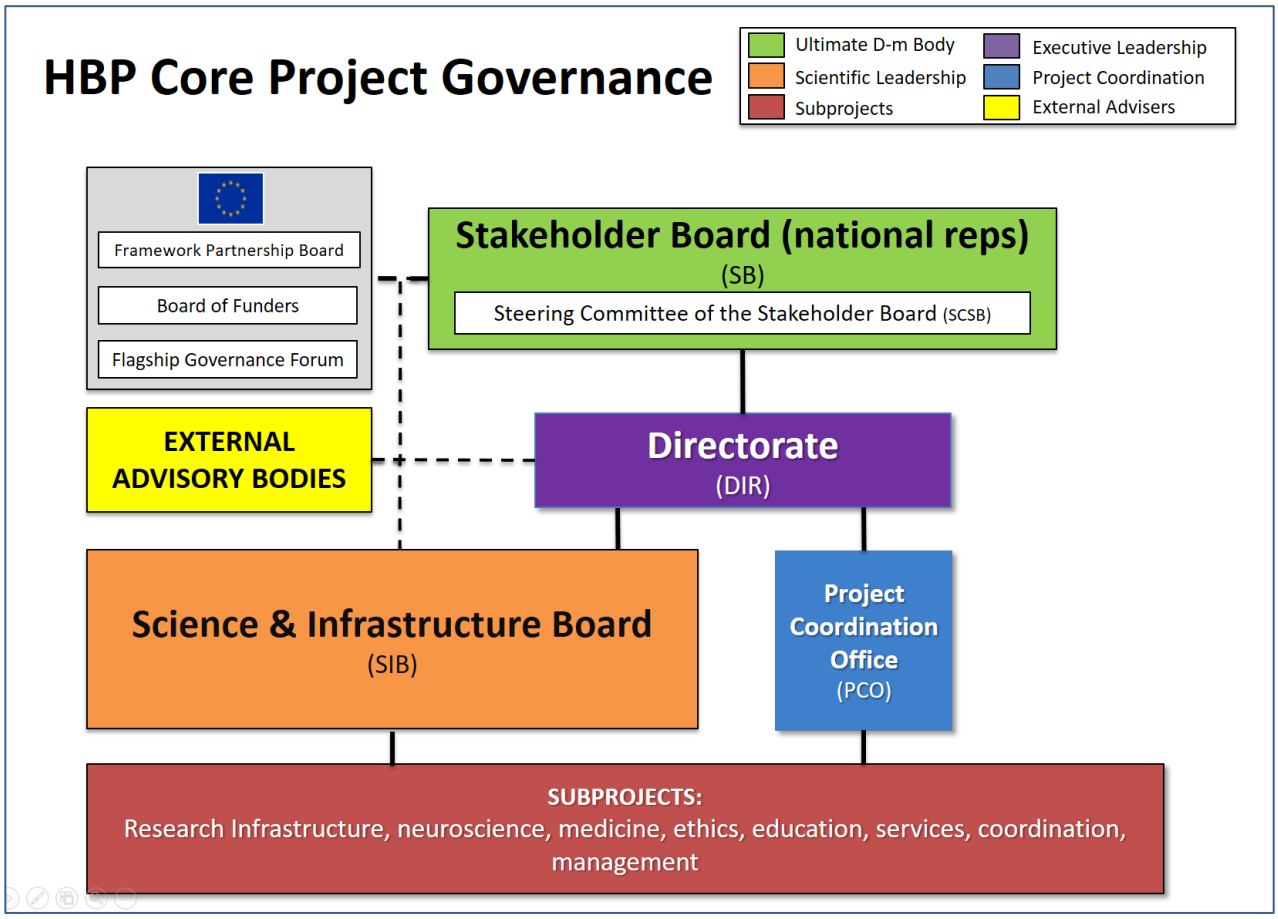

Figure 1: HBP Project Governance

3. Composition, Responsibilities and Functioning of the Governing Bodies

3.1 Internal Boards

3.1.1 Governing Bodies

3.1.1.1 Stakeholder Board (SB)

The Stakeholder Board (SB) is the ultimate decision-making body of the HBP.

3.1.1.1.1 Membership

The SB consists of one Member per country participating in the HBP Core Project. The HBP Partner organisations in each country select one person to represent them on the SB. All the Partner organisations within a participating country are required to provide a letter, co-signed by their authorised representatives, in which they formally nominate the SB member for their country. HBP Partner organisations are recommended to take the gender balance of the SB into consideration when selecting their national representatives.

The SB members must be free of conflicts of interest and therefore cannot be direct beneficiaries of HBP funds.

If a Member steps down, the HBP Partner organisations of that country have to collectively agree a replacement to fill the vacant seat within one month of the formal resignation of previous incumbent. If the seat is still empty after one month, the quorum for voting can be adjusted as described in the SB Terms of References (ToR) (Annex 1: Stakeholder Board Terms of Reference)

The current members of the Stakeholder Boards are listed here https://www.humanbrainproject.eu/en/about/governance/boards/stakeholder-board/

3.1.1.1.2 Tasks and responsibilities

The main responsibilities of the SB are:

1) Approving (or rejecting) Amendments to the FPA and SGAs, including:
    a. Approving the budget allocation to each Subproject, and which Partner Organisations will be active in each SGA;
    b. Approving material changes to the HBP Work Plan;
    c. Approving a change of Tasks, Work Packages or Subprojects (such as the creation of new Tasks, Work Packages or Subprojects, and the dissolution of existing ones), reallocation of work and budget between Subprojects, or change of the leader of a Subproject, Work Package or Task;
    d. Approving proposals to change the Coordinator;
    e. Approving the withdrawal of existing Parties from the FPA and the related consequences (such as reallocation of responsibilities to remaining Partners); and
    f. Approving the accession of new Parties to the FPA;
2) Supervising the Steering Committee of the Stakeholder Board (SCSB) with regard to the establishment of the HBP Legal Entity;
3) Appointing, suspending or dismissing Members of the DIR, SIB and Advisory Bodies;
4) Declaring an HBP Partner organisation to be a defaulting party; and
5) Approving the termination of a defaulting HBP Partner organisation's participation in the Consortium and related measures.

SB Members can propose topics for the SB to discuss, either in meetings or offline. They can also mandate SB working groups and committees on specific topics.

3.1.1.1.3 Decision-making process

The SB votes by electronic means or orally during meetings. An SB vote can be triggered by the DIR, SIB, PCO or the SB, but all such requests must be channelled through the Chair of the SB. Details on quorum and majority for voting can be found in the SB ToR (Annex 1: Stakeholder Board Terms of Reference) and in the HBP Consortium Agreement. All decisions are recorded in a Decision Register (Annex 2: Stakeholder Board Decision Register).

3.1.1.1.4 Meetings

The SB holds two to three meetings a year (in person or via tele/videoconference).

The agenda for each meeting is developed by the PCO in conjunction with the Director-General and Executive Director, and sent to the SB Chair for review and approval. Agendas are circulated to SB Members 10 days prior to the meeting. Additional details of the agenda process are set out in the SB ToR (Annex 1: Stakeholder Board Terms of Reference).

Twice a year, the DIR and the SIB give a status report about the progress of their work to the SB. The reports should be delivered respectively by the Director General and the Chair of the SIB. The

reporting format should use a traffic light system, allowing the SB to check easily if projects are on track or behind schedule, and the reasons for any deviation (Annex 3: Report to the Stakeholder Board). Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK.

3.1.1.2 Steering Committee of the Stakeholder Board (SCSB)

3.1.1.2.1 Membership

The Steering Committee of the Stakeholder Board (SCSB) is composed of SB Members from the countries participating in the HBP which receive the eight largest contributions in the current Special Grant Agreement (SGA).

The current members of the Steering Committee of the Stakeholder Board are listed here:

https://www.humanbrainproject.eu/en/about/governance/boards/stakeholder-board/

3.1.1.2.2 Tasks and responsibilities

The SCSB set up the SB and is now a Committee within the SB. Its main responsibility is to coordinate the creation of the new HBP Legal Entity that will take over the role of HBP Coordinator and will be responsible for the long-term management of the HBP Research Infrastructure, beyond the current 10-year EU-funded HBP Future and Emerging Technology (FET Flagship) Project.

3.1.1.2.3 Meetings

The SCSB meets as needed, normally about two or three times a year (in person or via tele/videoconference). Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK.

3.1.1.3 Directorate (DIR)

The Directorate (DIR) is the executive body in charge of the management of the Human Brain Project (HBP). The DIR reports to the SB and puts forward proposals for decisions to the SB. Chaired by the Director-General (DG), the DIR comprises seven Members from different fields of expertise, each appointed for the term of one SGA.

Other than the DG, the DIR Membership comprises the:

- Executive Director;
- Scientific Research Director;
- Software Development Director;
- Infrastructure Operations Director;
- Ethics Director;
- Innovation Director.

Three Members of the DIR (Scientific Research Director, Software Development Director, Infrastructure Operations Director) are also Members of the Science and Infrastructure Board (SIB), as can been seen in Figure 2 below. The Executive Director and Ethics Director are also regular guests at SIB meetings. This guarantees that the DIR is informed about the SIB discussion topics and decisions, and vice-versa.

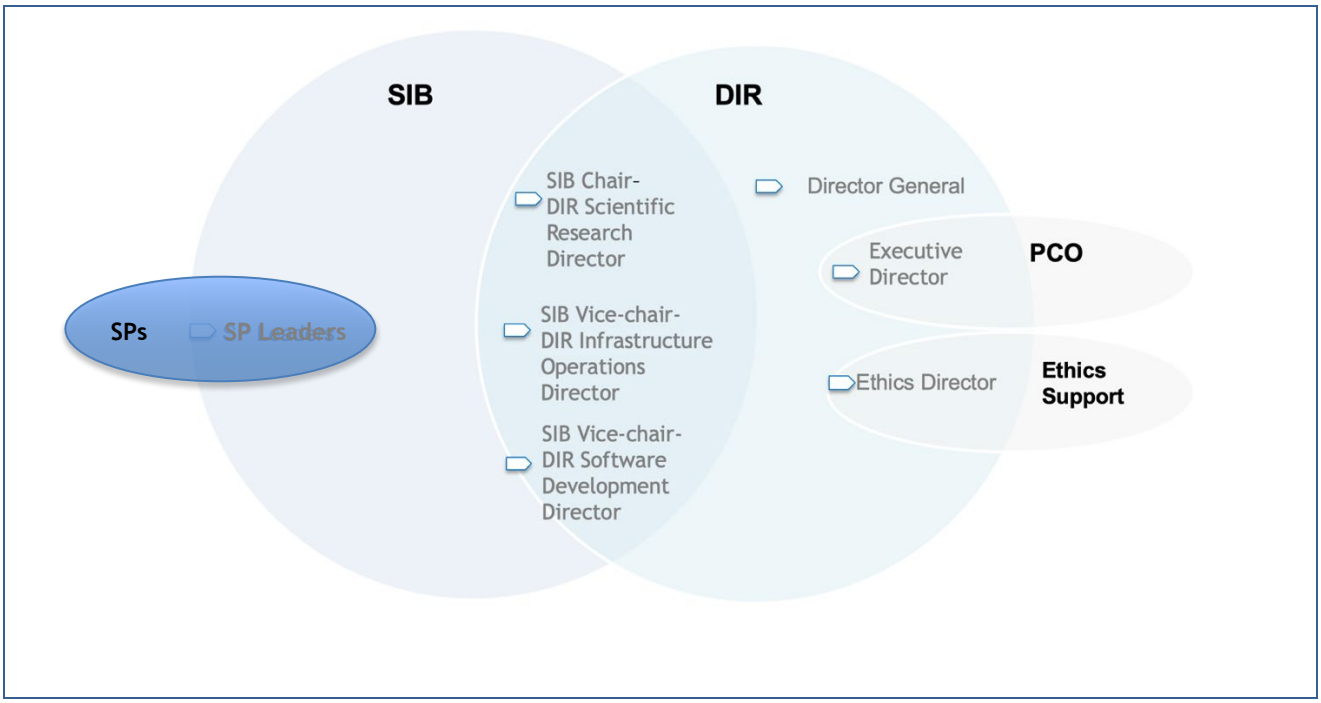

Figure 2: Overlap between the DIR and SIB membership

3.1.1.4 Tasks and responsibilities

The DIR is responsible for:

1) Monitoring that the HBP Consortium fulfils its obligations, as set out in the FPA, individual SGAs and the HBP Consortium Agreement;
2) Monitoring that the decisions of the SB are implemented appropriately;
3) Reviewing and approving or rejecting proposals and recommendations made by the SIB, in relation to SGA Work Plans, Scientific and Infrastructure Work Plans and related budgets, and submitting approved proposals and recommendations to the SB for confirmation;
4) Reviewing and approving or rejecting recommendations made by the SIB or PCO for amendments to existing agreements (including the FPA and SGAs), and submitting approved recommendations to the SB for confirmation;
5) Approving or rejecting proposals from the SIB or PCO for changes to the composition of the Consortium and submitting approved proposals to the SB for confirmation;
6) Assessing whether the Scientific and Infrastructure Work Plans and related budgets proposed by the SIB are achievable with the resources available and that they are appropriate for achieving the goals set in the FPA and successive SGAs;
7) Proposing to the SB, after consulting the SIB, the Partner Organisations that will be active in each SGA;
8) Monitoring that approved Scientific and Infrastructure Work Plans are implemented appropriately and that Milestones are met, in order to produce the planned products and Deliverables on time and to the required quality standard;
9) Adopting all audit reports and ensuring the implementation of any requested corrective measures; and
10) Requesting the SIB to take measures to address a breach of contractual obligations, and/or escalating such a procedure to the SB.

The DIR plays a key role in representing the HBP in external meetings and dissemination activities, and maintaining close relations with key stakeholders, especially the European Commission.

All the Members of the DIR serve as the public face of the Project; giving media interviews, providing remarks in press releases, and representing the HBP and its leadership at political, scientific and public events.

3.1.1.5 Role descriptions

3.1.1.5.1 The Director General (DG)

The Director-General (DG) serves as the head of the DIR. The DG is employed by the Coordinator.

The DG works in close collaboration with the Executive Director and the Chair of the SIB (Science Research Director) and is responsible for:

- Leading the Directorate and its activities;
- Approving the appointment of new Members of the DIR and maintaining the bodies' Membership at an appropriate level;
- Functioning as the DIR's liaison with the EC and representing the HBP at the Board of Funders;
- Actively contributing to the establishment of the HBP Legal Entity.

The DG chairs DIR meetings and approves the proposed meeting agendas and meeting minutes before they are sent out to DIR Members.

The DG holds regular meetings with the Executive Director to receive updates on the daily management of the Project.

The DG will strive to resolve any issue that arises in relation to the executive management of the Project, in particular within the Project Coordination Office (PCO) and the DIR, and problems cannot be resolved through a regular governance vote.

3.1.1.5.2 The Executive Director (ExD)

The Executive Director (ExD) serves as deputy to the DG and head of the HBP's Project Coordination Office (PCO). The ExD is employed by the Coordinator. The ExD's responsibilities include:

- Leading the Management and Coordination Subproject (SP11) and the Project Coordination Office (PCO).
- Working in close collaboration with the DG, the Chair of the SB and the Chair of the SIB to ensure a smooth and efficient governance, and proper representation of the stakeholders of the Project in the governing bodies.
- Contributing to the establishment of the HBP Legal Entity and the HBP Research Infrastructure.

The ExD holds regular meetings with the DG and with the Chair of the SB to give them updates on the daily management of the Project.

The ExD is regularly invited to the Science and Infrastructure Board (SIB) meetings as a guest. He/she informs the SIB about SP11 coordination activities that require its involvement.

3.1.1.5.3 The Scientific Research Director (SRD)

The Scientific Research Director (SRD) is chosen by the Science and Infrastructure Board (SIB) and is also Chair of the SIB. The SRD is responsible for:

- Leading the Project's scientific research activities, in particular:

  - Leading the development of HBP's long- and short-term scientific strategy in the form of its scientific roadmap and work plan;
  - Foster and publish HBP high-level publications;
  - Serve as the Project's primary contact for future scientific collaborations; initiating and establishing international collaborations and representing the interests of the HBP within these collaborations.
- Chairing the SIB and ensuring the effective and transparent operation of that body.
- Ensuring the coherence and quality of any document produced by the SIB.
- Ensuring close cooperation between the SIB and the DIR, in pursuit of the HBP's objectives.
- Briefing the SB and DIR on the scientific progress of the project and any issues encountered, at intervals determined by the SB and the DIR chairs.
- Representing the SIB in the DIR and conversely, representing the DIR in the SIB. Bringing proposals from the SIB to the DIR and communicating requests from the DIR to the SIB.
- Coordinating the activities of the Scientific Advisory Board (SAB) and Clinical Advisory Board (CAB).

3.1.1.5.4 The Software Development Director (SDD)

The Software Development Director (SDD) is chosen by the SIB and is also Vice-Chair of the SIB. The SDD's specific responsibilities include:

- Defining the Project's Software Development strategy, with regard to the HBP roadmap and work plan.
- Coordinating the Project's software development activities: engaging with or participating in relevant committees (Joint Platform Steering Committee, Joint Infrastructure Coordination Committee), to ensure appropriate implementation of the work plan, and providing a direct link between these committees and Project governing bodies.
- Defining software development quality standards and coordinating their implementation.
  - These efforts address the developments related to the individual HBP Platforms, with a special emphasis on coordination and convergence of the Platforms toward the Joint Platform, in close collaboration with the Infrastructure Operations Director.
- Governance Support: Supporting the SRD in coordinating the activity of governing bodies. In particular, representing the SIB Chair in her/his absence, representing the SIB in the DIR and vice-versa.
- Outreach: Contributing to outreach activities, specifically:
  - Engaging with relevant scientific communities; in particular, with regard to developing the HBP Joint Platform's user base;
  - Initiating international collaborations; in particular, regarding use of the HBP Joint Platform.

3.1.1.5.5 The Infrastructure Operations Director (IOD)

The Infrastructure Operations Director (IOD) is chosen by the SIB and is also Vice-Chair of the SIB. The IOD is responsible for the coordination of the design, construction, operation and upgrading of the HBP Research Infrastructure. In close collaboration with Research Infrastructure stakeholders, the IOD is also responsible for ensuring the sustainability of the Research Infrastructure by ensuring the growth of its user base and securing its funding by Member States. The IOD's specific responsibilities include:

- Infrastructure strategy: driving the development of a coherent HBP Research Infrastructure which meets the needs of the research community, supports a broad range of research methodologies and facilitates data sharing, ICT services and collaborative research harnessing multiple disciplines and computing, and which is developed to address current and future challenges in neuroscience.
- Resources: Ensuring that sufficient HBP resources are allocated towards the principle goal of the Project: the development of its ICT-based Research Infrastructure.
- ESFRI / ERIC Roadmap: together with the PCO, lead the definition of a vision for the HBP Research Infrastructure attaining ESFRI or ERIC status and overseeing its implementation by HBP governing bodies.
- User support: leading a support structure to help external users and developers to use and contribute to the HBP Research Infrastructure.
- Comprehensive Service Level Agreement (SLA): together with the PCO, defining objectives for SLA to be offered to users of the HBP RI.

3.1.1.5.6 The Ethics Director (EthD)

The Ethics Director (EthD) is proposed by SP12 and appointed by the Ethics Advisory Board (EAB).

The Ethics Director is responsible for:

- Representing ethics-related activities and processes on the HBP Directorate.
- Interfacing with the European Commission:
  - Working with HBP Partner organisations to prepare ethics reviews.
  - Overseeing and coordinating ethics reviews.
  - Preparing responses to EC ethics reviews.
  - Leading HBP interactions with ethics audits.
- Working with the HBP Directorate and PCO to ensure that ethics management and Standard Operating Procedures (SOPs) are appropriately integrated in HBP management structures.
- Working with all scientific SPs and ensuring that ethics support and compliance management issues are addressed appropriately:
  - Heading annual trilateral meetings between the ethics support team, SP Leaders/Rapporteurs and EAB members, to discuss ethical issues relating to each SP.
  - Monitoring compliance and analysing regular reports on implementation of ethics-related SOPs in all SPs.
  - Overseeing the Ethics Rapporteur Programme.
  - Contributing to the Education Programme, to ensure it covers HBP ethics support activities.
- Attending all EAB meetings, and facilitating collaboration and communication between the EAB and the DIR, SIB and SP12.
- Prioritising ethical issues raised by the Point of Registration (PORE), in collaboration with SP12 Steering Committee and EAB
- Leading the Ethics Support Team:
  - Developing, overseeing and maintaining ethics management processes.
  - Ensuring that relevant information (if not confidential) is made publicly available.
- Contributing to the data governance working group.

- Establishing links with other initiatives using big data in health-related research to identify good practice.
- Ensuring that relevant ethics-related processes and practices are integrated into the HBP Legal Entity and HBP Research Infrastructure.
- Contributing to the dissemination and communication of ethics-related issues, working with SP12 and central communication.

In the event of an ethical breach (e.g. a failure to obtain the proper authorisation or consent for conducting research, or a data protection breach), the Ethics Director is responsible, with the support of the Ethics Support Team, for closely monitoring that breach in collaboration with the relevant stakeholders (the SP leader and Ethics Rapporteur of the SP from which the breach arises, the Data Protection Officer, the Ethics Advisory Board) and ensuring that the breach is resolved. The Ethics Director may at his/her own discretion escalate the matter to the DIR through the breach of contract and default procedure described in Section 4 of this Governance Handbook.

3.1.1.5.7 The Innovation Director (InD)

The Innovation Director (InD) has the following core responsibilities:

- Setting the course for the HBP's innovation strategy and accompanying its execution, in collaboration with the HBP Innovation Task Leader.
- Representing the Project at events related to innovation and technology transfer.
- Guiding the Innovation Task Leader in approaching key target users, thus contributing to raising visibility of HBP-developed technology, and engaging a pertinent audience in conversation.

The InD and the Innovation Task Leader agree on a balance between supply-driven innovation (identifying innovation-relevant technology developed, identify and engage users) and demand-driven innovation (identifying possible users, ascertain their needs).

3.1.1.5.8 DIR Membership

The current members of the Directorate are listed here:

https://www.humanbrainproject.eu/en/about/governance/boards/directorate/

3.1.1.6 Decision-making process

Decisions of the DIR are made by consensus wherever possible. In the absence of a consensus, decisions of a simple majority prevail. DIR meetings must have a quorum of two thirds for a decision to be taken. Voting is done either in person in meetings or electronically and can be triggered by the DIR itself or requested by the PCO. All decisions are recorded in the DIR Decision Register.

3.1.1.7 Meetings

The DIR meets every two or three weeks via videoconference. Three or four times a year, there are physical meetings. Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK. All governance-related documents can be found in the EMDESK document manager under Governance.

3.1.1.7.1 Agenda

In advance of each DIR meeting, a draft agenda containing the current topics is put together by the governance support function in the PCO. This draft goes to the ExD for further input and then to the

DG for approval. It is then shared with the DIR Members, together with the supporting documents for the meeting. DIR members can add new items to the agenda until the day before the meeting. At the beginning of each meeting, the DG formally asks if the DIR approves the agenda. Any DIR Member can bring up new topics which will be discussed under AOB (any other business) if there is no objection from the other Members.

Standing points on every agenda are:

- Approval of the meeting agenda
- Approval of the minutes of the last meeting
- Review of the action item list.

3.1.1.7.2 Minutes

During the meeting, one or two persons from the governance support function take the minutes. After the meeting, these are converted into executive minutes which highlight decisions and action items. The DG reviews the minutes. and after his approval, these are shared with the DIR. These can be commented on and corrected for up to one week after circulation. The minutes are approved at the next meeting under the second standing point of every meeting agenda.

3.1.1.7.3 Decision Register

Decisions, other than approval/rejection of minutes and agendas, are recorded in the Decision Register which is kept in the form of an MS Excel table (Annex 4 Directorate Decision Register). If the decision text is too long for the table, a pdf-document with the decision text is attached to the Decision Register.

3.1.1.7.4 Action Items List

Like the Decision Register, the Action Items List is a living document. It records all the identified action items in a to-do-list. The Action Item List is updated and assessed by the PCO before every DIR meeting. During each meeting, the DG goes through the list and asks for updates on all the items that are still open (Annex 5 Directorate Action Items List). Action items that are assigned to the PCO are delegated to the SP11 Manager for the follow up.

3.1.2 Science and Infrastructure Board (SIB)

The SIB is central to the HBP Core Project. It provides the scientific leadership of the HBP. It decides the scientific content and strategy of the Project and is responsible for proposing and implementing the scientific and infrastructure work plan agreed for each SGA. It reports to the SB via the DIR.

3.1.2.1 Membership

The SIB consists of the Leaders of each Subproject involved in the Scientific and Infrastructure Work Plan (SPs 1 to 10, and SP12). The Work Package and Task Leaders in a Subproject elect an SP Leader and propose candidates for SP Deputy Leader. It is recommended that SPs take the gender balance of the SIB into consideration when electing their Leaders. The elected SP Leader choses up to two Deputies from the proposed candidates. If the SP Leader is not able to attend a SIB meeting, one of the SP Deputy Leaders can represent the SP concerned in the SIB meeting and participate in its decision making.

Since October 2017, the SIB has had an additional Member without voting rights, who represents the HBP's Partnering Projects (PPs). Since September 2018, a CDP representative attends SIB meetings as a permanent guest without voting rights. The SIB is chaired by the Scientific Research Director of

HBP, who is supported by two Vice-Chairs, one being the Software Development Director and the other being the Infrastructure Operations Director. All Members of the SIB are elected and nominated for a term of one SGA.

The current members of the Science and Infrastructure Board and its chairs are listed here: https://www.humanbrainproject.eu/en/about/governance/boards/science-and-infrastructure-board/

3.1.2.2 Tasks and Responsibilities

1) Proposing, via the DIR, for approval by the SB, the scientific and infrastructure work plan and related budget allocation to each SP for each SGA.
2) Proposing to the DIR adjustments to the list of Partners in the HBP for each SGA, based on the SB-approved work plan for that SGA and the results of the formal EC review of the Project's performance during the previous SGA.
3) Proposing changes to the scientific and infrastructure work plans to take account of scientific and technological advances inside and outside the HBP.
4) Ensuring that the scientific SPs achieve the Objectives, Milestones and Deliverables set out in the relevant SGA.
5) Reassigning responsibilities to avoid any potential conflict between SPs in the implementation of the work.
6) Requiring an SP to implement changes in the performance of its work.
7) Identifying corrective actions and enforcing their implementation when an SP fails to provide adequate corrective action itself for underperformance with regard to fulfilment of SGA commitments.
8) Approving Partnering Projects and their Associated Members.
9) Preparing the scope for Calls for Expression of Interest for each SGA, in accordance with the procedure outlined in the FPA.
10) Appointing the scientific and implementation leaders for HBP Co-Design Projects.
11) Initiating and participating in outreach activities.
12) Establishing and contributing to international collaborations.
13) Reporting to the HBP Advisory Boards on a regular basis.
14) Engaging with scientific communities, Member States and funding agencies.

3.1.2.3 Decision-making process

SIB decisions shall normally be taken during SIB meetings and, in exceptional cases, by electronic vote, with a quorum of two thirds of members and a simple majority. Each SP involved in the scientific and infrastructure work plan (SPs 1 to 10, and SP12) has one vote. Votes can be triggered by the SIB itself or requested by the PCO. All decisions are recorded in the SIB Decision Register.

3.1.2.4 Meetings

The SIB meets every two or three weeks via videoconference. Three or four times a year, there are physical meetings. Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK.

3.1.2.4.1 Agenda

A draft agenda containing the current topics is put together by the SIB coordinator in advance of an SIB meeting. This draft goes to the SIB Chair for further input and approval. It is then shared with the SIB Members together, with the supporting documents for the meeting. SIB Members can add new items to the agenda until the day before the meeting. At the beginning of each meeting, the SIB Chair formally asks if the SIB approves the agenda. Every SIB Member can bring up new topics which will be discussed in AOB (any other business) if everyone agrees.

Standing points on every agenda are:

- Approval of the meeting agenda
- Approval of the minutes of the last meeting

3.1.2.4.2 Minutes

During the meeting, minutes are taken by the SIB Coordinator. After the meeting, the minutes are firstly approved by the SIB Chair and after his/her approval, they are shared with the SIB by the SIB Coordinator. The minutes can be commented on and corrected for up to one week after they are first circulated. They are approved during the next meeting as the second standing point of every meeting agenda. Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK.

3.1.2.4.3 Decision Register

Decisions, other than approval/disapproval of minutes and agendas, are recorded in the Decision Register in the form of an MS Excel table (Annex 6 Science and Infrastructure Board Decision Register). If the decision text is too long for the table, a pdf-document with the decision text is attached to the Decision Register.

3.1.2.4.4 Action Items List

Like the Decision Register, the Action Items List is a living document. It records all the identified action items in a to-do-list. The Action Item List is updated and assessed by the SIB coordinator before every SIB meeting (Annex 7 Science and Infrastructure Action Items List).

4. Non-Governing Structures

4.1 Project Coordination Office (PCO)

The Project Coordination Office (PCO) is the unit within the Coordinator organisation (currently the EPFL) that manages and coordinates the HBP and acts as an intermediary between the HBP Consortium and the European Commission (EC). It is headed by the Executive Director. The PCO's coordination responsibilities are:

1) Maintaining the HBP work plan (budget) and administering the EU contribution.
2) Assisting the SIB in compiling SGA work plans and related budgets, prior to review by the DIR and approval by the SB.
3) Coordinating the planning, writing and timely submission to the EC of SGA Proposals and Amendments.
4) Monitoring and supporting the implementation of the work plan by the SPs.

5) Identifying emerging problems and helping to manage them, as foreseen in Section 4.2 of the HBP Consortium Agreement.
6) Pre-screening Partnering Project proposals, forwarding each one for evaluation by two SP Leaders who have no conflict of interest, and forwarding their recommendations on acceptance or rejection of the proposal to the SIB.
7) Monitoring and facilitating the integration of Partnering Projects (PPs) in the HBP Flagship.
8) Coordinating the Subprojects to support key cross-cutting committees e.g. Gender, Scientific Research Data, Software Development, infrastructure Operations, Ethics and Innovation.
9) Providing central services and support across the HBP.
10) Coordinating standards development within the HBP and with external standardisation bodies.
11) Collecting, reviewing and submitting Reports and Deliverables to the DIR and EC.
12) Communicating any decisions on approved Partnering Projects to the HBP Partner organisations.
13) Supporting the DIR, SB and SCSB by planning and organising the meetings, taking minutes and ensuring follow up of the decisions taken during their meetings.
14) Supporting the Research Infrastructure by building and operating the Collaboratory (Portal for the RI, collaborative tools), the Knowledge Graph and PLUS (the HBP's in-house project management database).

4.2 Subprojects (SPs)

Each Subproject has a SP Leader, at least one Deputy SP Leader and an SP Manager. Each Subproject is responsible for its own internal governance structure which should:

- Be focused on successful and timely completion of the Subproject's Milestones and Deliverables.
- Take into account the interests of the HBP Partner organisations in that Subproject.
- Resolve any issues within the SP that may affect other parts of the HBP or the HBP Consortium.
- Signal to the SIB and DIR any issues within the SP that may affect that SP, other parts of the HBP or the overall HBP Consortium which the SP has not been able to resolve.

The Work Package and Task Leaders in a Subproject elect an SP Leader and propose at least one candidate SP Deputy Leader from among their Members. The elected SP Leader choses up to two Deputies from the proposed candidates. It is recommended that SPs taken the gender balance of the SIB into account when electing their Leaders. If an SP Leader steps down from that position or leaves the HBP, a new Subproject Leader must be elected.

The SP Leader is responsible for:

1) Monitoring SP Members' compliance with their obligations set out in the HBP FPA, SGAs and the HBP Consortium Agreement.
2) Collecting, reviewing and submitting high-quality Reports and Deliverables to the Project Coordination Office.
3) Proposing to the SIB, based on the decision of the Subproject, a requested change in the allocation of the financial contribution to that Subproject.
4) Reviewing Partnering Project proposals that are associated with his/her Subproject and submitting his/her recommendation to the SIB (via the PCO) to accept or reject them.

4.3 Co-Design Projects (CDPs)

Co-Design Projects (CDP) are groupings that bring together Tasks and resources from multiple SPs to achieve cross-cutting objectives, that help to advance science while contributing to the development of the HBP Research Infrastructure. They focus on the delivery of specific key products, comprising a number of constituent components. All the activities of the CDPs are contained in the Work Plan of the Subprojects.

Any new CDP should be proposed by one or more HBP Partner Organisations and approved by the SIB. Each CDP is headed by two CDP Leaders: a CDP Scientific Leader, and a CDP Implementation Leader. Their nomination is part of the proposal; both are then confirmed by the SIB.

The CDP Leaders are responsible for the success of their CDP and its timely delivery of high-quality Products, Deliverables and Reports, as specified in each SGA.

4.4 Advisory Boards

The role of the Advisory Boards is to provide advice to the SIB and the DIR in support of the development of strategy of the HBP, as well as scientific and ethical questions. This will include the identification of future priorities and opportunities to be pursued by the HBP and the development of plans of action to address priorities, integrating activities across SPs and Platforms with a view to developing a sustainable Research Infrastructure. Reports of the Advisory Boards are forwarded to the SB.

Advisory Board Members are not employed or funded by HBP Partner Organisations.

The current Advisory Boards are:

- The Ethics Advisory Board (EAB), created in September 2015
- The Clinical Advisory Board (CAB), created in March 2017
- The Scientific Advisory Board (SAB), created in March 2017

4.4.1 Ethics Advisory Board (EAB)

The EAB is an independent body that advises the SIB and DIR on specific ethical, regulatory, social and philosophical issues raised by research that is being undertaken or planned under the auspices of the HBP.

The advisory status of an EAB recommendation means that individual researchers, investigators, laboratories and institutions retain their full legal responsibilities under the terms of local, national and international regulations, as well as any professional obligations that they may be subject to.

4.4.1.1 Membership

EAB members 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.

Each EAB member is assigned to two SPs, in line with their expertise and competence.

Further details on membership, covering new appointments, renewals and terminations can be found in the EAB SOP (Annex 8 Ethics Advisory Board Standard Operating Procedure)

The current members of the EAB are listed here:

https://www.humanbrainproject.eu/en/about/governance/boards/ethics-advisory-board/

4.4.1.2 Tasks and responsibilities

The EAB may offer its advice on its own initiative, as well as in response to requests made by HBP researchers or other participants in the Project, about specific ethical, regulatory and social issues arising from research undertaken within the HBP or by its collaborators.

Each Subproject in the HBP has at least one Ethics Rapporteur (ER).

Annual trilateral meetings are held with each SP. Each meeting is attended by the SP Leader and/or Deputy, ER- and/or SP Manager, at least one EAB Member affiliated to that SP, and members of the Ethics Support team headed by the Ethics Director. Ethical issues in each SP are discussed and are included in one-pagers which are worked on jointly by the respective ERs and EAB Member for that SP. EAB Members may additionally be invited to their affiliated SP meetings, typically during the HBP Summit.

The collaboration and communications between the EAB, the DIR, SIB and SP12 is facilitated by the Ethics Director who attends all EAB meetings who is responsible for the Ethics Support Work Package.

4.4.1.3 Chairs

The EAB has a Chair and a Vice Chair. The EAB elects its Chairs from among its Members. The tenure of the Chairs is two years, renewable for a further two years. The Chair has the following roles:

- Representation of the EAB towards the HBP and external bodies
- 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 Support team in planning and executing meetings, agendas, etc.
- Ensuring quality assurance for EAB opinions or other official statements

4.4.1.4 Decision-making process

The decision making process of the EAB is set out in its SOP (Annex 8 Ethics Advisory Board Standard Operating Procedure). Generally, decisions of the EAB are made by consensus. Where no consensus can be reached, decisions are made based on use of a simple majority. Each Member has one vote which can be transferred to a proxy.

4.4.1.5 Meetings

The EAB has three in-person meetings per year. One of these meetings is co-located with the HBP Summit. Teleconferences are organised in due course between each physical EAB meeting. The EAB receives support to organise its meetings and follow-up through the Ethics Support team.

4.4.2 Clinical Advisory Board (CAB)

The CAB is an independent body that advises the SIB on all clinical issues. This includes strategy and planning activities, promoting the optimal use of the research platforms and infrastructure facilities, and issues related to cooperation with other research institutions and initiatives.

4.4.2.1 Membership

CAB Members are unpaid experts who are chosen for their knowledge in a specific area relevant to the HBP. Membership is determined by competence, geographical and gender balance. The CAB values diverse perspectives.

The CAB is led by a Chair who is supported by a Vice Chair. Both, the Chair and Vice Chair, are elected from by its members for two-year period, which can be renewed for another 2 years. Additional details on membership, ranging from new appointments to renewals and terminations can be found in the CAB SOP (Annex 9 Clinical Advisory Board Standard Operating Procedure)

The current members of the CAB are listed here:
https://www.humanbrainproject.eu/en/about/governance/boards/clinical-advisory-board/

4.4.2.2 Tasks and responsibilities

The CAB may offer its advice on its own initiative, as well as in response to requests made by researchers or other participants in the Project, or committees and boards of the HBP, within its remit, especially, in the context of reviews and in case of potential underperformance of individual Subprojects or HBP Partner organisations.

The CAB also works closely with the Chair of the SIB.

The CAB uses an electronic mailing list to communicate all information relevant to all of its members.

The CAB Chair has the following roles:

- Representation of the CAB to the HBP and external bodies,
- Representation of the CAB at reviews,
- Organising the working structure of the CAB,
- Communicating relevant information to the CAB members,
- Working with the PCO in planning and executing meetings, agendas, etc.,
- Ensuring quality assurance for CAB opinions or other official statements.

4.4.2.3 Decision-making process

Decisions of the CAB are made with a quorum of two thirds and by consensus, wherever possible. Where no consensus can be reached, decisions are made based on use of a simple majority. Each Member has one vote which can be transferred to a proxy.

Further details can be found in the CAB's SOP (Annex 9 Clinical Advisory Board Standard Operating Procedure).

4.4.2.4 Meetings

The CAB has two meetings per year. One of these meetings is co-located with the HBP Summit. Meetings of the CAB are attended by:

- CAB Chair and members,
- SIB Chair and Deputy Chairs, when required,
- Director General or Executive Director, when required,
- Further invited participants when required.

Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK.

4.4.3 Scientific Advisory Board (SAB)

The SAB is an independent body that advises the HBP, in particular the SIB and the DIR on all scientific and technical issues. This includes the HBP strategy and planning activities, promoting the optimal use of the research platforms and infrastructure facilities, and issues related to co-operations with other research institutions and initiatives.

4.4.3.1 Membership

SAB Members are unpaid experts are chosen for their knowledge in a specific area relevant to the HBP. Membership of the SAB is determined by competence, geographical and gender balance. The SAB values diverse perspectives.

The SAB is led by a Chair who is supported by a Vice Chair. Both, the Chair and Vice Chair, are elected from by its members for two-year period, which can be renewed for another 2 years.

The current members of the Science Advisory Board are listed here https://www.humanbrainproject.eu/en/about/governance/boards/scientific-advisory-board/

Additional details on membership, ranging from new appointments to renewals and terminations can be found in the SAB SOP (Annex 10 Scientific Advisory Board Standard Operating Procedure).

4.4.3.2 Tasks and responsibilities

The SAB may offer its advice on its own initiative as well as in response to requests made by researchers or other participants in the Project, or committees and boards of the HBP, within its remit, especially, in the context of reviews and in case of potential underperformance of individual Subprojects or HBP Partner organisations.

The SAB also works closely with the Chairs of the SIB, the DIR and the SB.

The SAB uses an electronic mailing list to communicate all information relevant to all of its members.

The SAB Chair has the following roles:

- Representation of the SAB to the HBP and external bodies,
- Representation of the SAB at reviews,
- Organising the working structure of the SAB,
- Communicating relevant information to the SAB members,
- Working with the PCO in planning and executing meetings, agendas, etc.,
- Ensuring quality assurance for SAB opinions or other official statements.

4.4.3.3 Decision-making process

Decisions of the SAB are made with a quorum of two thirds and by consensus, wherever possible. Where no consensus can be reached decisions are made based on use of a simple majority. Each member has one vote which can be transferred to a proxy.

Further details can be found in the SAB's SOP (Annex 10 Scientific Advisory Board Standard Operating Procedure).

4.4.3.4 Meetings

The SAB has two meetings per year. One of these meetings is co-located with the HBP summit.

Meetings of the SAB will be attended by:

- SAB Chair and Members,
- SIB Chair and Vice-Chairs, when required,
- Director General or Executive Director, when required,
- Further invited participants, when required.

Approved minutes of the meetings are made available to the Consortium through the project management platform EMDESK.

4.5 Individual experts

4.5.1 Data Protection Officer (DPO)

The Data Protection Officer (DPO) is a data protection professional who works with HBP Partner organisations to facilitate their compliance with the General Data Protection Regulation (GDPR), an EU Regulation that came into force on 25 May 2018. The role of the DPO includes consultation on data processing activities and providing advice and recommendations on compliance with the GDPR and other applicable laws. In particular, the DPO helps SPs and HBP Partner organisations to carry out data protection impact assessments (DPIAs) and other compliance tasks.

In addition to data protection compliance, the DPO has a liaison function and consults with data subjects, HBP Partner organisations and leadership, and supervisory authorities.

4.5.2 Ombudsperson (OP)

The Ombudsperson (OP) is an experienced, independent, neutral person whose role is to assist in resolving conflicts where other mechanisms are insufficient or fail to offer a protected environment to encourage the reporting of potential issues within the HBP without fear of retribution. The OP's role includes:

- Support the resolution of serious conflicts of interest;
- Prevention and remedy of otherwise unjustified actions;

Potential subjects include protection of scientific integrity or prevention of misconduct where the relevant existing processes are unlikely to be sufficient. If the conflicting parties do not find a solution or obey the advice of the OP, the OP reports to the DIR with recommendations on how the DIR should act. If the DIR is involved in the conflict, the OP reports to the SB. If need be, the OP can address actors outside the HBP.

Additional details on the role of the Ombudsperson can be found here:
https://www.humanbrainproject.eu/en/about/hbp-ombudsperson/

5. Breach of Contract and Default

If an SP Leader or any HBP Governing Body identifies, or is informed of, a breach of contract by an HBP Partner organisation, notably a failure to fulfil its obligations under the FPA, an SGA or the HBP Consortium Agreement (e.g. the improper implementation of the Work Plan), the SP Leader or the Chair of that governing body must inform the PCO. The PCO should inform the DIR of the breach and request the SP Leader of the SP in which the breach has occurred to take measures to remedy the

breach. The request should include a reasonable deadline for submitting to the DIR and PCO a proposal for remedying the breach. The SP Leader may request the DIR to grant an additional grace period for submitting a proposal for remedy of the breach.

At any time during the procedure described above, the DIR may unilaterally request the SIB to take measures to prevent further escalation of the breach or to take corrective action to remedy it. Any such request by the DIR should include a reasonable deadline for submitting a proposal for remedy to the DIR and PCO. Corrective actions proposed by the SIB may include a request to reallocate work and associated budgets between Tasks and/or Work Packages within the SP concerned, or between SPs, or a change of Partners involved, or a change of leadership at any level.

If the SIB is unable to submit a proposal for remedying the breach within the specified deadline, or it becomes obvious that the breach cannot be remedied by the proposed corrective measures, the DIR may unilaterally decide to submit its own remedy proposal directly to the SB for approval. The DIR may include in its submission:

- A proposal to reallocate work and associated budgets between Tasks and/or Work Packages within the SP concerned, or between SPs, or a change of Partners involved, or a change of leadership at any level; or
- A proposal to declare an offending HBP Partner organisation to be a Defaulting Party as per the HBP Consortium Agreement, if the breach is substantial or forms a substantial part of the volume of the work allocated to that HBP Partner organisation.

6. Conflicts of interest

Each HBP Partner organisation is responsible for preventing any conflict of interest, as defined in the FPA:

"The partners must take all measures to prevent any situation where the impartial and objective implementation of the specific actions is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests').

They must formally notify to the Commission without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Commission may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline."

An HBP Partner organisation cannot simultaneously have its employees serving as the Chair of more than one of the following Governing Bodies: the DIR or SIB. The SIB Chair and Vice-Chairs cannot be employees of the same HBP Partner organisation.

Members of HBP Governing Bodies and Advisory Boards are required to declare interests that may lead to potential conflicts relating to their respective role in the HBP when they are appointed. The overall Register of Interests is maintained by the HBP Ethics Support team and is available to any member of the HBP or the public upon request.

All Members are required to review and update their interests annually. Further details on the Register of Interests can be found in the Conflict of Interest SOP (Annex 11 Conflict of Interest Standard Operating Procedure).

7. Principal topics requiring SIB, DIR and SB attention

7.1 Proposals for new SGAs, Amendments to the FPA and existing SGAs

The SIB is responsible for preparing an agreed work plan for each Proposal for a new SGA. It is also responsible for updating the work plan as required in any Amendment of the FPA and/or existing SGAs. The PCO collaborates closely with the SP Managers to coordinate the drafting of Proposals for a new SGA and the drafting of Amendments to the FPA and existing SGAs.

All such Proposals and Amendments must be reviewed and approved by the DIR. The PCO then submits all Proposals and Amendments on behalf of the DIR to the SB for approval.

7.2 Deliverables, Project Reports and Project Reviews by the European Commission

The PCO and SPs, through their SP Managers, collaborate closely in the drafting of Deliverable and Project Reports. The contents of these documents do not require formal review and/or approval by the SIB, DIR or SB, but the SIB and DIR are responsible for the quality of those Deliverables and Project Reports, as well as their timely submission to the European Commission.

The PCO, SPs, the DIR and SIB also collaborate closely to prepare the formal Project Reviews conducted by the European Commission.

8. Next Version of the Governance Handbook

The next version of the HBP Governance Handbook will include new sections about the HBP Committees and, if applicable, updated ToR of the SB and updated SOPs of the EAB, CAB and SAB.

9. Glossary

CA	Consortium Agreement
CAB	Clinical Advisory Board
CDP	Co-Designed Projects
DPIA	Data protection impact assessments
DG	Director General
DIR	Directorate
EAB	Ethics Advisory Board
EMDESK	Project management software
ER	Ethics Rapporteur
ERIC	European Research Infrastructure Consortium
ESFRI	European Strategy Forum on Research Infrastructures
EthD	Ethics Director

ExD	Executive Director
FET	Future Emerging Technologies
FPA	Framework Partner Agreement
GDPR	General Data Protection Regulation
ICT	Information and Communication Technology
InD	Innovation Director
IOD	Infrastructure Operations Director
LE	Legal Entity
OP	Ombudsperson
PLA	Project Life-cycle Application
PLUS	Dashboard to support coordination of the project (successor to the PLA)
PP	Partnering Projects
SAB	Science Advisory Board
SB	Stakeholder Board
SCSB	Steering Committee of the Stakeholder Board
SDD	Software Development Director
SGA	Special Grant Agreement
SIB	Science and Infrastructure Board
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SP	Subproject
SRD	Science and Research Director
ToR	Terms of Reference

Annex 1: Stakeholder Board Terms of Reference

(The contents of this Annex are confidential)

Annex 2: Stakeholder Board Decision Register

(The contents of this Annex are confidential)

Annex 3: Report to the Stakeholder Board

(The contents of this Annex are confidential)

Annex 4: Directorate Decision Register

(The contents of this Annex are confidential)

Annex 5: Directorate Action Items List

(The contents of this Annex are confidential)

Annex 6: Science and Infrastructure Board Decision Register

(The contents of this Annex are confidential)

Annex 7: Science and Infrastructure Action Items List

(The contents of this Annex are confidential)

Annex 8: Ethics Advisory Board Standard Operating Procedure

(The contents of this Annex are confidential)

Annex 9: Clinical Advisory Board Standard Operating Procedure

(The contents of this Annex are confidential)

Annex 10: Scientific Advisory Board Standard Operating Procedure

(The contents of this Annex are confidential)

Annex 11: Conflict of Interest Standard Operating Procedure

(The contents of this Annex are confidential)