

Swiss Personalized Health Network: Rules of Procedure (5.12.2016; revised on 27.2.2018, 20.2.2020)

Preamble

“Personalized Medicine” (PM) is in rapid development worldwide as emphasized again by the recent initiation of a “Precision Medicine Initiative” (PMI) (now called “All of Us”) in the USA and/or the Summary on Personalized Medicine of the European Academies Science Advisory Council. In Switzerland, a national research initiative “Systems Medicine – Personalized Health”, the so-called “Swiss Personalized Health Network (SPHN) Initiative”, was proposed by the Federal Council in its ERI Dispatch 2017-2020.

This initiative aims at creating a national “Swiss Personalized Health Network” (SPHN) that integrates all relevant Swiss research institutions and organizations (e.g. University Hospitals and Universities, ETH-Domain institutions, SIB Swiss Institute of Bioinformatics, Swiss National Science Foundation [SNSF], Federal Office of Public Health [FOPH]) as well as ongoing related projects (e.g. Swiss Biobanking Platform [SBP], Human Biomonitoring/Cohort Project [HBCP], the ETH-Domain Strategic Focus Area in Personalized Health and Related Technologies [PHRT]) in order to cooperate by joining forces nationwide, to include all available competences and to coordinate the required infrastructures all over Switzerland.

Between 2017-2020, the SPHN consortium will receive a total amount of CHF 68 million. Rules on how and according to which criteria these funds are to be invested were elaborated in 2017.

The participating institutions strive to achieve the highest scientific quality in the field of personalized medicine and, through their collaboration within the framework of SPHN, establish for themselves a worldwide reputation of excellence.

Article 1.

Purpose

The Swiss Personalized Health Network (SPHN) has the following objectives:

- (a) Coordinate the national and international collaboration of the institutions in the field of personalized medicine research;
- (b) Establish various items of infrastructures, e.g. technology platforms and in particular a National Data Coordination Center;
- (c) Coordinate the financial contributions for research infrastructure including the national Data Coordination Center in the field of personalized medicine;
- (d) Foster R&D and communication in the field of personalized medicine;
- (e) Coordinate and intensify the cooperation between research institutions, public and private health institutions and organisations, politics and public administration;
- (f) In collaboration with partners of the Swiss Academies of Arts and Sciences, participate in the dialogue in and with the public on personalized medicine;
- (g) Secure additional external funding.

Article 2.

Governing Bodies

The SPHN has the following governing bodies:

- (a) National Steering Board (NSB);
- (b) National Advisory Board (NAB);
- (c) Ethical Legal Social Issues Advisory Group (ELSlag);
- (d) International Advisory Board (IAB);
- (e) Data Coordination Center (DCC);
- (f) Management Office (MO).

As a rule, the members of the NSB (a) and the ELSlag (c) provide their services in an honorary capacity. They are entitled to compensation for their out-of-pocket expenses. Mandates executed by the members which exceed the work in connection with the meetings of the bodies can be compensated according to a separate compensation directive. The directive also includes a section on the compensation of the International Advisory Board. Members of the bodies are expected to attend at least 50% of the meetings of their respective board. If a Board Member's presence is below this threshold, the Chairperson will discuss with that Board Member the viability of her/his continued involvement on the Board. In the case of a Representative Board Member (NSB), the Chairperson will also notify the appropriate eligible organization.

(a) National Steering Board (NSB)

Article 3.

Duties and Powers of the NSB

1. The NSB reports regularly to SERI, the contracting authority. It also communicates on a regular basis with other political authorities (i.e. Cantonal Public Health Ministers). It is coordinated by the SAMS in collaboration with partners such as for example the SNSF and FOPH.
2. The NSB is the highest governing body of the SPHN. It has overall strategic responsibilities for the whole initiative including the coordination of data standards and interoperability, the integration of SBP and HBCP, and Personalized Health platforms at Universities and University Hospitals and ETH-Domain institutions.
3. In particular, the NSB exercises the following duties and powers:
 - a. Within the framework of the mandate given by the political authorities, determining the SPHN's strategic focus (incl. requirements of data infrastructure, data semantic, scope of coordination, etc.) and initiating discussions on the next funding period;
 - b. Decide on funds allocation based on the funding principles and upon proposal of the IAB;
 - c. Appoint and dismiss the Chairperson of the NSB (and her/his Vice-Chair); the Chairperson shall be an elected Council Member of the SAMS;
 - d. Appoint and dismiss the members of the NAB; Appoint the Chairperson of the NAB (and her/his Vice-Chair);

- e. Appointing an ELSIag, its Chairperson, as well as prescribing the ELSIag's tasks and powers in separate rules;
- f. Appointing an IAB and prescribing the IAB's tasks and powers in separate rules;
- g. Approve the annual business plan and budget of the DCC;
- h. Approve and dismiss the Managing Director;
- i. Annual report to the political authorities;
- j. Approve the business plan prepared and submitted by its Ausschuss and the yearly budget and the yearly management report including accounting;
- k. Approve the Rules of Procedure and the Funding Principles of SPHN;
- l. Supervise the activities of the other governing bodies;
- m. Promote the SPHN's goals in industry;
- n. Report yearly to the SPHN Partners if wished;
- o. Represent the SPHN Initiative to the outside, in collaboration with the Ausschuss according to the communication concept;
- p. Determining who shall be entitled to sign on SPHN's behalf.

Article 4.

Composition | Appointment | Term of Office

1. The NSB is composed of about 17 members which represent University Hospitals (3; 1 "Lausanne-Geneva-(Bern)" cluster; 1 "Zurich-Basel" cluster; 1 Verband für Universitäre Medizin), swissuniversities (3; including 1 representative of the Universities of Applied Sciences), ETH-Domain (2; 1 ETHZ and 1 EPFL), SNSF (1; SNSF representative), Patient organisation (1), SIB (1; SIB Director), SAMS (2; president/vice-president plus 1 additional council member) and others (max. 3), plus the Chairperson of the NAB, Chairperson of the ELSIag, the DCC Director, the Managing Director, and representatives from the Confederation (SERI and/or FOPH) without rights to vote. The represented institutions can propose the NSB members, and they are elected by the SAMS.
2. The Chairperson of the NSB and her/his Vice-Chairperson are appointed every four years and may be reappointed.

Article 5.

Meetings

1. There are at least three NSB meetings per year.
2. The meetings are convened by the Chairperson or by the Vice-Chairperson at least ten days before the meeting in writing and specifying the agenda.
3. A member of the NSB may request an additional meeting by giving written notice to the Chairperson specifying the agenda and the motions to be considered. It shall be convened following the same procedure as for the other meetings.

4. Minutes of each meeting shall be kept. A member may request that her/his motions, including a statement of justification, or her/his rejection of a resolution be recorded in the minutes. The minutes are shared with the SERI and all NSB members.

Article 6.

Resolutions

1. In the meetings, each member has one vote. Each member can nominate one permanent empowered proxy who may vote on her/his behalf.
2. Quorum shall be reached if at least half of all members entitled to vote are present.
3. The meetings shall adopt resolutions with the majority of votes.
4. Votes shall be cast by a show of hands. Any member may request a secret ballot.
5. Resolutions may also be adopted by circular letter (email), provided no member requests an oral discussion.

Article 7.

Ausschuss of the NSB

The Ausschuss (AS) meets regularly to prepare and advance activities, process information, and enable more effective management of the SPHN as a whole. The AS is not an executive decision-making body, unless the NSB gives a mandate to the AS. The AS has the duty to prepare the NSB meetings.

The AS is composed of the NSB Chair & Vice-Chair, the NAB Chair, the ELSI Chair, the DCC Director, the SIB Director, the MO, a representative of PHRT as a guest.

(b) National Advisory Board (NAB)

Article 8.

Duties and Powers of the NAB

The NAB is an advisory body to the entire SPHN. The NAB is not an executive decision-making body, unless the NSB gives a mandate to the NAB.

In particular, the NAB has the following duties:

1. **Infrastructure Roadmap:** Provide advice on health research infrastructure development to the National Steering Board (NSB), the Data Coordination Center (DCC), and the BioMedIT Board, similar as the ELSI advisory group does for ethical aspects of the initiative;
2. **National SPHN Landscape:** Coordinate, examine and address issues related to health research infrastructures and their operations. Contribute to national efforts of harmonization of research infrastructures. Identify and report issues to the NSB, DCC and/or to the BioMedIT Board;
3. **Gap Analysis:** Identify gaps and areas with need for action in close collaboration with the SPHN driver projects, infrastructure providers, and working groups of the DCC;
4. **Mandated SPHN Working Groups:** Formulate mandates for solving those issues by bespoke expert working groups. Monitor the establishment, progress and timely elaboration of the mandate deliveries of the working groups.

5. **International Benchmark:** Contextualize SPHN efforts within the international landscape. Evaluate new technologies, standards, and processes resulting out of SPHN projects or international efforts and make recommendations regarding their endorsement and implementation in the SPHN ecosystem.

Article 9.

Composition | Appointment | Term of Office

1. The NAB should be composed of a Chairperson and a maximum of 3-4 members covering the following core domains of SPHN:
 - a. Patient, hospital, and citizen aspects;
 - b. ICT architecture and interoperability;
 - c. Analytical technologies (e.g. *omics platforms);
 - d. Health data management, life cycle, interoperability, bioinformatics.
2. The members of the NAB shall have the experience and insight to identify strategically relevant infrastructural issues within SPHN requiring solutions, and the competences to steer and coordinate the SPHN Working Groups responsible for tackling specific mandates.
3. Members of the NAB should be strongly involved in the infrastructural aspects / developments of SPHN and able to dedicate time and commitment to the Initiative.
4. The members of the NAB and the Chairperson shall be appointed by the NSB following a call for nominations. Eligible are members of SPHN partner institutions. They shall be appointed to office for a term of four years and may be reappointed.
5. The NAB shall coopt a representative of the DCC and of the Management Office (MO) without a right to vote.
6. The Chairperson of the NAB participates in NSB meetings with a consultative vote.

Article 10.

Meetings | Working principles

1. The NAB shall meet as often as the business may require, but no less than three (3) times a year.
2. The meetings shall be called by the Chairperson of the NAB or by the representative of the DCC on her/his behalf. In addition, every member of the NAB may request the convocation of a meeting by the Chairperson by submitting a written agenda for the meeting to be called.
3. In case an issue is discussed in which a NAB member has vested interests, she/he will have to withdraw from the discussion.
4. The principle of "ad personam participation" shall apply; participation of proxy shall not be allowed.
5. The NAB shall propose the formation and funding of "Mandated SPHN Working Groups" to the NSB.
6. External/international experts as well as representatives from the working groups shall be co-opted on an ad-hoc basis without a right to vote, where needed.
7. Efforts by the NAB can be financially supported by SPHN according to the SPHN bylaws.

Article 11.

Expert Pool | Mandated SPHN Working Groups

1. The NAB shall assemble a group of scientific experts (Expert Pool) with in-depth knowledge of the field of personalized health who are prepared to serve as members of Mandated SPHN Working Groups.
2. Members of the Expert Pool shall be regularly informed by the SPHN DCC and the MO about the

latest developments and progress of SPHN to allow them to act efficiently as part of their role within the Mandated SPHN Working Groups.

3. The integration of experts working in specific disease areas (e.g. oncology, immunology) in the Expert Pool should be encouraged.

(c) Ethical Legal Social Issues Advisory Group (ELSlag)

Article 12.

1. The ELSI advisory group treats ethico-legal challenges that the SPHN Initiative will face related to Ethical, Legal and Social Implications. It supports adherence to the Human Research Act (HRA) and the Federal Act on Data Protection.
2. The ELSlag shall develop robust ethical policies anticipating well-known challenges such as that of appropriate informed consent and privacy. Also, it should develop mechanisms and processes that will be ready to handle issues that have not been anticipated and will require a swift resolution.
3. The ELSlag shall play a key role in the development of such mechanisms. It provides advice to NSB and NAB, but also to the SPHN projects.
4. The ELSlag shall advise the NAB and NSB in the development of policies for data sharing and managing questions of intellectual property, authorship and attribution according to national and international standards.
5. Review projects funded by SPHN and provide guidance to the investigators. The ELSlag reports to the NSB regularly.
6. The ELSlag shall coordinate with other groups/initiatives who pursue the same goals.
7. Based on its important and multiform significance, the composition of the ELSlag must be diversified and should consist of about 9 members including representatives of the following fields/organizations: Bioethics (2), SAMS (1), swissethics (1), Life Sciences Law (1), Social Sciences (1), others (max. 3).

(d) International Advisory Board (IAB)

Article 13.

1. An International Advisory Board (IAB) provides international advice, expertise, and peer-review of specific funding proposals and of the initiative as a whole.
2. The IAB should be composed of international experts and has a core of eight to ten members. The Chairperson of the IAB shall be appointed by the IAB members itself.

(e) Data Coordination Center (DCC)

Article 14.

The DCC is managed by SIB and is responsible for the definition of common technical data standards, harmonization of semantics, data storage formats, data security, database management and quality control. The DCC links to university and hospital IT departments, biobanks, and the registries of existing and new cohorts. In essence, the DCC ensures the interoperability of the various clinical and –omics data.

In particular, the DCC has the following duties:

1. Define common technical data standards, harmonize semantics, data storage formats, data security, database management and quality control;
2. Organize annual tests to assess the shareability and interoperability of data as prescribed in the Collaboration Agreement between SAMS and the University Hospitals;
3. Assess and communicate to the MO if the projects funded by SPHN have met their milestones;
4. Present an annual business plan and budget to the NSB and provide regular updates;
5. Coordinate and manage their advisory groups (e.g. DCC Working Groups);
6. Coordinate with the MO on matters of communication, meeting organization, calls for proposals, and website updates.

(f) Management Office (MO)

Article 15.

1. The MO shall be responsible for the daily operations of the SPHN.
2. The MO shall be directed by a Managing Director; the Managing Director reports directly to the Chairperson of the NSB.
3. The MO shall be integrated at the offices of the Swiss Academy for Medical Sciences (SAMS) in Bern. The SAMS shall provide the necessary infrastructure for the Management Office.
4. The MO provides administrative support to all SPHN bodies (i.e. NSB, NAB, ELSIag, IAB) and punctual working groups as well as to the whole SPHN Initiative as required by the actual needs.
5. Communication (internal as well as external) will be an important part of the SPHN. This will be organized and coordinated by the MO in coordination with SAMS.
6. Salaries and running costs for the MO shall be financed through Federal Funds.
7. Essentially, the MO shall have the following duties:
 - a. Prepare the agenda for the meetings of the NSB, the AS, the NAB, the IAB and punctual working groups together with their respective Chairperson and record the minutes of the meetings;
 - b. Support the implementation of the resolutions by the NSB;
 - c. Organize, direct and control the daily operations of the SPHN Initiative;
 - d. Report, control and prepare the budget;
 - e. Ensure timely and effective information flow between the MO, NSB, AS and NAB, ELSIag;
 - f. Ensure the information flow between the various partner institutions, and in particular between SNSF, PHRT, SERI, FOPH.

Article 16.**Participation of Third Parties**

1. Bodies of SPHN (NSB, AS, NAB, ELSlag, DCC, MO) may invite interested third parties, e.g. representative of authorities, health sector, industry, politics or international research institutions, but also employees of the individual Partners as permanent or non-permanent guests to the meetings. By decision of the respective body, invited third parties may be excluded from the discussion and voting procedures concerning certain issues. Third parties shall be bound to confidentiality.
2. Permanent and non-permanent guests shall not have the right to vote or move a motion.

Governance**Article 17.****Business Year**

The business year of SPHN shall be the calendar year.

Article 18.**Financing**

1. SPHN's financing shall be ensured by the yearly contributions of the Confederation and the private sector (Third Party Fund from industry, SME etc) to the SAMS and the SIB.
2. SPHN funds shall be transferred in tranches to the institutions according to decisions by the NSB.
3. For the implementation of the approved projects, payments to the individual Partners shall be made in accordance with the regulations of the SAMS.

Article 19.**Power to Sign**

The Chairperson and Vice-Chairperson of the NSB are authorized to sign legally binding documents on behalf of the SPHN together with another member of the NSB board or the Managing Director. The NSB is responsible for appointing additional persons with authority to sign on behalf of the SPHN and specifying the details of the authority. Documents that are not legally binding can be signed by the Chairperson, the Vice-Chairperson or the Managing Director alone.

Article 20.**Accounting Records, Reporting and Audit**

1. SPHN shall have its own accounting records.
2. The accounting and annual reporting of SPHN Federal funds shall be administrated by the SAMS and by the SIB respectively.
3. The audit shall be carried out by a third party company.
4. MO reports to the NSB. The NSB must approve any report sent to external bodies e.g. SERI, FOPH.

Final Provisions

Article 21.

Amendments

1. In order to be put to the vote, a motion proposing an amendment to the Rules of Procedure must be submitted by a member to the Chairperson of the NSB in writing at least thirty days prior to a meeting.
2. To amend the Rules of Procedure, a resolution passed by the majority of the members present at a meeting is required.

These Rules of Procedure were approved by the National Steering Board on 20.2.2020 and replace the previous version from 29.5.2018 with immediate entry into force.