Swiss Personalized Health Network:
Rules of Procedure

(5.12.2016; revised on 27.2.2018, 20.2.2020, 10.5.2021)

Preamble

"Personalized Health" is rapidly developing worldwide as emphasized by, for instance, the initiation of a "Precision Medicine Initiative" (PMI) (now called "All of Us") in the USA and 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 and renewed in the ERI Dispatch 2021-2024.

This initiative aims at creating a national "Swiss Personalized Health Network" (SPHN) that integrates all relevant Swiss research institutions (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]) and research organizations (e.g., Swiss Clinical Trial Organisation [SCTO], Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung [SAKK]) 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 nationwide, to include all available competences and to coordinate the required infrastructures all over Switzerland.

Between 2017-2020, the SPHN consortium received a total amount of CHF 68 million. For the second funding period 2021-2024, CHF 66.9 million are allocated to SPHN. Rules on how and according to which criteria these funds are to be invested were elaborated in 2017 and revised in 2021.

The participating institutions strive to achieve the highest scientific quality in the field of personalized health and, through their collaboration within the framework of SPHN, establish 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 health research;

(b) Establish various items of sustainable infrastructures, e.g., technology platforms and in particular a National Data Coordination Center, and consolidate them until completion of the initiative;

(c) Coordinate the development and implementation of semantic and technical standards and of harmonized processes to promote interoperability of clinical and health-related data across institutions;

(d) Coordinate the financial contributions for research infrastructure including the National Data Coordination Center in the field of personalized health;

(e) Clarify the ethical and legal issues linked to the use and sharing of clinical and health-related data for research;

(f) Foster R&D and communication in the field of personalized health;

(g) Coordinate and intensify the cooperation between research institutions, public and private health institutions and organizations, politics and public administration;

(h) In collaboration with partners of the Swiss Academies of Arts and Sciences, participate in the dialogue in and with the public on personalized health;

(i) Develop a strategy for public-private partnerships in personalized health.

(j) Establish and promote best practices and templates in human research involving further use of data with regard to patient safeguard and data protection, validity and reproducibility.

Article 2.
Governing Bodies

The SPHN has the following governing bodies:

(a) National Steering Board (NSB);

(b) National Advisory Board (NAB);

(c) Hospital IT Strategy Alignment Group (HIT-STAG);

(d) Ethical Legal Social Issues Advisory Group (ELSIag);

(e) International Advisory Board (IAB);

(f) Data Coordination Center (DCC);

(g) Management Office (MO).

As a rule, the members of the NSB (a) and the ELSIag (d) provide their services in an honorary capacity. They are entitled to compensation for out-of-pocket expenses. Mandates executed by the members that 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 (e.g., cantonal public health ministers). It has a direct link with the SAMS (who elects the NSB members) and collaborates with partners such as 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

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and HBCP, and personalized health platforms at universities, 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 SPHN's strategic focus (incl. requirements of data infrastructure, data semantic, scope of coordination, etc.), consolidate the network, ensure completion of the initiative and clarify the transfer of the Data Coordination Center in a long-term, regular structure;

   b. Decide on funds allocation based on the SPHN Funding Principles and according to the SPHN Funding Regulations;

   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. Appoint and dismiss the members of the ELSIag, its chairperson, as well as prescribing the ELSIag's tasks and powers in separate rules, should they go beyond these Rules of Procedure;

   f. Appoint and dismiss the members of the IAB, its chairperson and prescribing the IAB's tasks and powers in separate rules, should they go beyond these Rules of Procedure;

   g. Approve the annual business plan and budget of the DCC;

   h. Approve and dismiss the managing director after consultation of the SAMS. The employment is through the SAMS;

   i. Report annually to the political authorities;

   j. Approve the business plan prepared and submitted by its Ausschuss (the NSB committee, see Article 7) with the yearly budget and yearly management report including accounting;

   k. Approve the SPHN Rules of Procedure, Funding Principles, Funding Regulations, Compensation Regulations and Call Documents;

   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 a communication concept;

   p. Determine who shall be entitled to sign on SPHN's behalf.

Article 4.
Composition | Appointment | Term of Office

1. The NSB has about 17 members, which represent university hospitals (5 members; 1 representative of each university hospital, of which at least 1 representing also unimedsuisse), 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) and

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others (max. 3). Additional members with only consultative votes are the chairperson of the NAB, chairperson of the ELSIag, chairperson of the HIT-STAG, the DCC director, the managing director, and representatives from the Confederation (SERI and/or FOPH) serving as ex officio members. The represented institutions can propose the NSB members, and they are elected by the SAMS. Each NSB member may designate one person (with a similar strategy-level position at the represented institution) as permanent proxy. Permanent and non-permanent guests can, in addition, be invited to NSB meetings but do not have a right to vote (see Article 19). Board members (or their deputies) should not participate at the same time in strategic boards and as well as in operative working groups, unless it is explicitly requested by the NSB.

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. Policies, guidelines and framework documents elaborated by working groups and task forces mandated by the NSB, shall be submitted for a minimum of two readings to the NSB and be sent four weeks before the meeting to allow each NSB member to collect and consolidate feedback from stakeholders within their institution.

4. 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.

5. Minutes shall be kept of each meeting. 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 full NSB 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 or by recording electronic votes in case the meeting is held via videoconference. Any member may request a secret ballot.

5. Resolutions may also be adopted by circular letter (email), provided no member requests an oral discussion.

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Article 7.
Ausschuss of the NSB

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

The NSB-A is composed of the NSB chairperson & vice-chairperson, the NAB chairperson, the ELSIag chairperson, the HIT-STAG chairperson, the DCC Director, the SIB Director, the MO and, as a permanent guest a representative of PHRT.

(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 mandates 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, in a similar way as the ELSI advisory group does for ethical aspects of the initiative and the HIT-STAG for IT architecture related to university hospitals;
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, HIT-STAG, 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, HIT-STAG 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 5-6 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.
    e. Data analytics (scientific expert in advanced statistics or AI/ML approaches applied to clinical data related to personalized health research)
    f. *omics data (scientific expert in genomics, proteomics, or metabolomics data analysis

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related to personalized health research)

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. Infrastructural issues and mandates pertaining mainly to university hospital information systems shall be the responsibility of HIT-STAG.

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 ex officio with a consultative vote.

Article 10.
Meetings | Working Principles

1. The NAB shall meet as often as 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.

(c) Hospital IT Strategy Alignment Working Group (HIT-STAG)

Article 11.
Duties and Powers of the HIT-STAG

The HIT-STAG is an advisory body to the entire SPHN. The HIT-STAG is not an executive decision-making body, unless the NSB mandates the HIT-STAG.

In particular, the HIT-STAG has the following duties:

1. **Infrastructure Roadmap:** Provide advice on the SPHN IT infrastructure landscape and roadmap impacting university hospitals, in close collaboration with the DCC and the BioMedIT Board (comparable to the ELSI advisory group's activities for addressing ethical aspects of the initiative and to the NAB's activities for research-related aspects). Validate that the roadmap provides realistic goals, measures, milestones, and deliverables for hospital information systems;

2. **Oversight of implementation:** Monitor the implementation of agreed standards and infrastructures within university hospitals, based on qualitative and quantitative indicators;

3. **SPHN funded projects:** Align priorities of SPHN funded IT projects between university hospitals, considering feasibility and resources, in close collaboration with the SPHN driver projects, infrastructure providers, NAB, and working groups of the DCC;

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Article 12.
Composition | Appointment | Term of Office

1. The HIT-STAG is composed of five (5) persons: one senior representative of each university hospital IT management staff. One of the HIT-STAG members is appointed chairperson. The HIT-STAG shall coopt a representative of the DCC, the NAB, and of the Management Office (MO) without a right to vote.
2. The members of the HIT-STAG and the chairperson shall be appointed by the NSB. They shall be appointed to office for a term of four years and may be reappointed.
3. The chairperson of the HIT-STAG participates in NSB meetings ex officio with a consultative vote.

Article 13.
Meetings | Working principles

1. The HIT-STAG shall meet as often as business may require, but no less than three (3) times a year.
2. The meetings shall be called by the chairperson of the HIT-STAG or by the representative of the DCC or of the MO on her/his behalf. In addition, every member of the HIT-STAG may request the convocation of a meeting by the chairperson by submitting a written agenda for the meeting to be called.
3. The principle of "ad personam participation" is desired to ensure alignment at the strategic level. Proxy participation of senior hospital IT members is possible in well justified situations.
4. External/international experts, representatives from the working groups and guests shall be co-opted on an ad-hoc basis without a right to vote, where needed.
5. Efforts by the HIT-STAG can be financially supported by SPHN according to the SPHN bylaws.

Article 14.
Mandated SPHN Working Groups/Task Forces

1. The NSB can mandate groups of experts with in-depth knowledge of the field of personalized health with specific tasks and work packages.
2. The mandates of SPHN Working Groups/Task Forces shall be clearly formulated and the monitoring of the progress on the mandate assigned to one of the SPHN Governing Bodies.
3. Efforts by mandated Working Groups/Task Forces can be financially supported by SPHN according to the SPHN bylaws. Working Groups/Task Forces can apply for further funding to the NSB.

(d) Ethical Legal Social Issues Advisory Group (ELSIag)

Article 15.
Duties and Powers of the ELSIag

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 ELSIag develops robust ethical policies anticipating well-known challenges such as those concerning appropriate informed consent and privacy. Also, it should develop mechanisms and processes that can be applied to handle issues that have not been anticipated and require a swift resolution.
3. The ELSIag plays a key role in the development of such mechanisms. It provides advice to NSB, NAB and HIT-STAG, but also to the SPHN projects.

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4.   The ELSIag advises the NAB, HIT-STAG, 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 ELSIag reports to the NSB regularly.

6.   The ELSIag coordinates with other groups/initiatives that pursue the same goals as the ELSIag (as defined above).

7.   Based on its important and multiform significance, the composition of the ELSIag must be diverse and should consist of about nine (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).

(e) International Advisory Board (IAB)

Article 16.
Duties and Powers of the IAB

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 (8) to ten (10) members.
3. The members of the IAB and the chairperson shall be appointed by the NSB.
4. The IAB members are financially compensated by SPHN according to the SPHN bylaws.

(f) Data Coordination Center (DCC)

Article 17.
Duties and Powers of the DCC

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. Furthermore, the DCC facilitates data exchanges between SPHN partners on the governance and technical level. 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, –omics, and other health-related 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.   Facilitate and monitor the implementation of technical data standards, harmonized semantics, data storage formats, data security, database management and quality control at SPHN partner institutions;

3.   Facilitate data exchanges between SPHN partners by supporting streamlined governance processes and technical guidance;

4.   Assess the shareability and interoperability of data;

5.   Assess and communicate to the MO if the projects funded by SPHN have met their milestones;

6.   Present an annual business plan and budget to the NSB and provide regular updates;

7.   Coordinate and manage technical working groups/task forces;

8.   Coordinate with the MO on matters of communication, meeting organization, calls for proposals, and website updates.

(g) Management Office (MO)

Article 18.
Duties and Powers of the MO

1.   The MO is responsible for the daily operations of the SPHN.

2.   The MO is directed by a managing director; the managing director reports directly to the chairperson of the NSB.

3.   The MO is 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 (NSB, NAB, HIT-STAG, ELSIag, IAB) and punctual working groups / task forces as well as to the whole SPHN initiative as required by the actual needs.

5.   Communication (internal as well as external) is an important part of the SPHN. This shall be organized and coordinated by the MO in coordination with SAMS and SIB.

6.   Salaries and running costs for the MO are financed through federal funds.

7.   Essentially, the MO shall have the following duties:

    a.   Prepare the agenda for the meetings of the NSB, the NSB-A, the NAB, the HIT-STAG, the IAB and punctual working groups / task forces 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, NSB-A and NAB, HIT-STAG, ELSIag;

    f.   Ensure the information flow between the various partner institutions, and in particular between SNSF, PHRT, SERI, FOPH.

Article 19.
Participation of Third Parties

1.   Bodies of SPHN (NSB, NBS-A, NAB, HIT-STAG, ELSIag, 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

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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 make a motion.

Governance

Article 20.
Business Year

The business year of SPHN shall be the calendar year.

Article 21.
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 22.
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 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 23.
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.

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Final Provisions

Article 24.
Amendments

1. 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 or confirmed by a vote by circular is required.

These Rules of Procedure were approved by the National Steering Board by circular decision on 10.5.2021 and replace the previous version from 20.2.2020 with immediate entry into force.