Swiss Personalized Health Network: Funding Regulations (01.03.2017)

approved by the State Secretariat for Education, Research and Innovation on 01.03.2017.

The National Steering Board of the Swiss Personalized Health Network based on

the Message ERI 2017-2020 (BFI-Botschaft 2017-2020),

the Final report "Vorbereitung Implementierung Aufbauorganisation SPHN-Initiative" (15.12.2016),

the Rules of Procedure of the Swiss Personalized Health Network (05.12.2016),

the White paper "Funding Principles of the Swiss Personalized Health Network" (01.03.2017),

the Report of the SPHN Data Expert Group (27.01.17) as accepted by the SPHN Executive Board (31.01.17) and the SPHN National Steering Board (09.03.17),

the Zusatzprotokoll zur Leistungsvereinbarung 2017-2020 zwischen der Schweiz. Eidgenossenschaft und der Schweizerischen Akademie der Medizinischen Wissenschaften SAMW im Rahmen der "Swiss Personalized Health Network (SPHN)" Initiative (01.03.17).

issues the following Regulations:

Chapter 1 Scope of SPHN funding

The **long-term** goal of the Swiss Personalized Health Network (SPHN) is to establish a Swiss Network in Personalized Medicine/Health, in which **all** relevant biomedical research institutions, University (and other research) Hospitals, research funding organisations, Public Health institutions/ authorities (e.g. FOPH) and patient/citizen organisations are included.

In the first **period 2017-2020**, funding priority is given to the development of a nationally coordinated data infrastructure ensuring data interoperability of local and regional information systems. This will optimize the use of health-related data from both patients as well as healthy citizens for research.

SPHN will fund the additional effort/capacity (e.g. software, personnel) necessary to make clinical phenotype data interoperable and usable for research and to link them with other types of human data (e.g. *–omics* data, imaging data, lab data etc.). The overall database of SPHN needs to be built following a nationwide project matrix including:

(i) **horizontal initiatives (projects)** that are "devoted to build a progressive shareable interoperable data system", a dynamic, transparent and shared consent management and a core support of technical platforms;

(ii) **vertical initiatives (projects)**, that include the development of infrastructures and research based "driver" projects developing and testing new technologies, methods and infrastructures for personalized health related research.

The task list of shareable data infrastructures to be implemented and/or developed include Clinical Research Data Warehouses, Semantic Interoperability and Data Quality, Data Security, Bioinformatics and Data Analytics, Interoperability with Biobanking, Training facilities, a national Data Coordination Center, and research based "driver" projects.

Chapter 2 Types of funding and funding schemes

2.1 Funding principles (see white paper "Funding Principles")

1. Projects have to demonstrate a clear and practical step forward towards nationwide data interoperability including clinical phenotypes, life style data, –*omics* data, imaging data, lab data.
2. Projects must convincingly demonstrate adherence to the data sharing principles between all SPHN partners as defined by the ELSIag which will elaborate legally and ethically appropriate solutions for data access, privacy and trust. Access to encoded data and anonymised data for all SPHN partners shall be guaranteed and granted at no cost by partner institutions.
3. The matching funds principle applies to all financial contributions, i.e. the participating institutions must provide their own contributions (in cash and/or in kind) to match the funds provided by SPHN.
4. Research projects are not excluded, but must contribute to the infrastructures and/or apply methods towards obtaining nationwide data interoperability and a data sharing network (so-called "driver" projects).
5. Ethical legal and societal implications (ELSI) associated with personalized health research should be addressed within all SPHN funded proposals.
6. SPHN is under no obligation to award a grant to any person or entity.

2.2 Types of projects

SPHN shall support projects that fall into one of the following categories:

a. Projects for **infrastructure implementation** (top-down DEG horizontal initiatives; collaboration agreements [Leistungsvereinbarung]);
b. Projects for **infrastructure development** based on work packages (bottom-up horizontal and vertical initiatives; contributions);
c. **"Driver" projects** (vertical initiatives; contributions). Such "driver" projects are based in a concrete research field (e.g. cancer research/oncology) and drive the development of appropriate infrastructures to ensure nationwide data interoperability within the perspective discipline. Milestones are infrastructure-based, not research-based.

Funding of **ELSI activities** shall be included in each of the three project categories.

2.3 Funding schemes

SPHN distinguishes between two funding schemes:

a. **Collaboration agreements** (Leistungsvereinbarungen) for infrastructure implementation projects;
b. **Competitive calls** for infrastructure development and "driver" projects.

2.4 Collaboration agreements (Leistungsvereinbarungen)

1. For the implementation of defined and nationally coordinated data infrastructures, SPHN will establish collaboration agreements (Leistungsvereinbarungen) comprising deliverables and a milestone-based payment mechanism.
2. In case of multi-year funding, achievement of the defined milestones will be evaluated by the NSB on a yearly basis.
3. The next payment will be released only if the planned milestones have been reached to a sufficient degree.

2.5 Competitive calls for proposals

1. SPHN will organize targeted calls for project proposals addressing technical, scientific, ethical and policy challenges to reach the shareable data infrastructure goals aimed for by of the initiative; call contents will be based on the task list outlined in Chapter 1.
2. The proposals will be evaluated and prioritized by the International Advisory Board (IAB) (see Chapter 4).

2.6 Available funding (2017-2020)

A total budget of CHF 68 million is available for the period 2017-2020:

	Item	CHF	Description
1.	**Management, bodies, symposia, workshops, etc**	**4.0 mio**	**Limit of expenses (Ausgabenplafond)**
2.	**Horizontal & vertical project types (see section 2.2)**[1]	**46.0 mio**	**Total engagements (Verpflichtungskredit)**
a)	Projects for infrastructure implementation		Collaboration agreements (Leistungsvereinbarung)
b)	Projects for infrastructure development		Contributions
c)	"Driver" projects (vertical initiatives)[2]		Contributions
3.	**BioMedIT**	**18.0 mio**	**Limit of expenses (Ausgabenplafond)**

Remarks:

- *Unused funds in Line 1 and Line 3 can be transferred to Line 2.*
- *The matching funds rule applies to Lines 2 and 3 only.*

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[1] Project types are listed in order of priority. Hence, a) and b) will be funded first. Once the required infrastructure according to the DEG report is established, remaining funds may be used for c).
[2] Estimated frame: CHF 6-10 mio; not contractually binding.

- *The following exceptions have to be considered:*
  a) *BioMedIT is under the responsibility of SIB. No matching funds rule is applied for BioMedIT, except for delocalized funds.*
  b) *Funds allocated to SIB for the DCC are treated under Line 2a; no matching funds rule is applied.*

Chapter 3   Requirements for applicants and for submitting an application

3.1 Eligibility criteria

1. Main applicants should be Swiss higher education institutions (ETH-Domain, Universities, Universities of Applied Sciences) and University Hospitals. Translational aspects are mandatory and joint-applications are encouraged.
2. SPHN partner institutions are organised in two clusters:
   a. The "Bern-Geneva-Lausanne": CHUV/UniL, EPFL, HUG/UniGE, Inselspital/UniBe;
   b. The "Zurich-Basel" cluster: ETHZ, USB/UniBas, USZ/UZH;
3. In the case of applications for infrastructure implementation (collaboration agreements [Leistungsvereinbarung]), University Hospitals should submit an application with a support letter from the respective University. In order to ensure adherence to the principle of free data sharing among the research community, no direct funding to a University Hospital will be granted without a written agreement document from the respective University.
4. Wider participation is also desired, i.e. other Universities, research institutions and/or hospitals and industry are encouraged to associate with an institution of one of the two clusters and to make joint applications together with at least one SPHN partner institution.
5. SPHN funds can only be provided to Swiss higher education institutions (ETH- Domain, Universities, Universities of Applied Sciences) and University Hospitals. Private sector institutions must cover their efforts with their own resources.

3.2 Setting up a consortium

1. The main applicant is responsible for setting up a consortium for his proposal.
2. Under certain circumstances (e.g. no Swiss research group can provide the respective know-how), it is possible to include research groups located in a foreign country. However, they cannot be funded.

Note: SPHN funds can only be used for Swiss academic partners. The private sector partners must cover their efforts with their own resources.

3.3 Funding duration & conditions

1. Engagements for approved projects may last for a maximal duration of three years.
2. Funds can only be allocated until 31 October 2020.
3. The NSB will decide an overall award budget for each call and for each collaboration agreement (Leistungsvereinbarung).
4. A letter specifying and confirming own contributions (see Funding Principles, section 5.3) by the main applicant's institution must be attached to the proposal.

5. No overheads shall be paid for SPHN funded projects.

Chapter 4   Evaluation procedure

4.1 Proposal pre-screening

1. The selection of the proposals will be preceded by a formal check by the Management Office (MO).
2. Proposals which fail to comply with the formal requirements will not be admitted to the next stage of the selection procedure and will be rejected if the defect cannot be easily corrected.
3. The following formal requirements must be met:
   a. Compliance with the submission deadline;
   b. Completeness of the proposal, written in English;
   c. Eligibility of the main applicant and co-applicant(s);
   d. Acknowledgement of the need for the provision of own contributions in the case the proposal is approved for funding;
   e. Acknowledgement of the data sharing principles;
   f. Compliance with the actual Funding Regulations of SPHN.

4.2 Selection criteria for infrastructure implementation projects (collaboration agreements)

1. Each collaboration agreement will feature an infrastructure implementation plan.
2. Infrastructure implementation plans will be reviewed by a subgroup of the DEG who will verify that the technical requirements defined in the DEG report are met.
3. The DEG subgroup will submit recommendations to the NSB.

4.3 Selection criteria for infrastructure development projects and "driver" projects

1. Proposals will be reviewed by the IAB who may appoint additional experts to assist them with the assessment.
2. Proposals will be selected according to the following criteria:
   a. Fit within the task list outlined in Chapter 1;
   b. Contribution to the implementation of a nationwide harmonisation of molecular and clinical data semantics and of health information technology systems in order to achieve nationwide data interoperability;
   c. Integration of research data and clinical data in a common system;
   d. Focus to develop the necessary IT and data infrastructures to achieve nationwide common data standards;
   e. For driver projects, scientific quality, including added value of the project as a whole;
   f. Quality of the data sharing plan;
   g. Financial planning in general and distribution of the funding (total costs, own contributions, federal grant applications, third party funding).

3. The evaluation will be made in due consideration of the personalized health approach and of the significance for SPHN.
4. The IAB will submit funding recommendations to the NSB.

4.4 Funding decision

1. The NSB will decide on funds allocated to projects.
2. If necessary, short-listed main applicants may be invited to present their proposal and discuss it with the NSB.
3. Upon approval, a contract (grant contract or collaboration agreement) will be established between SPHN and successful applicants which will detail the following (see Chapter 5 and 6):
   a. Total amount awarded (engagement) and funding duration;
   b. Payment conditions;
   c. Reporting obligations.

Chapter 5   Grants and grant management

5.1 Legal consequences of the award

1. On the full or partial approval of a grant application (award), the applicants become grantees of SPHN.
2. Grantees are obliged:
   a. to use the grant in accordance with the conditions set out in the ruling;
   b. to comply with the provisions stipulated in these Regulations and all other rules applicable to the grant.
3. The grantees must provide the MO with a written summary of the planned project that is understandable to non-experts (lay summary). They must also provide thematic keywords for the SPHN website.
4. The lay summary and keywords must be submitted upon receipt of the funding decision, but no later than upon submission of the release of funds request.

5.2 Changes to project proposal

Substantial changes to the work, tasks and milestones described in the project proposal and/or set by the NSB as conditions for financing may only be made if requested in writing and approved by the MO.

5.3 Project withdrawal or termination

1. Applicants who withdraw their proposals or are forced to terminate it prematurely must inform the MO in written form stating reasons.
2. Any unused funds must be reimbursed.

5.4 Amendment and revocation of the award

1. If the prerequisites for the award are no longer met after approval of the award or if the circumstances on which approval is based change considerably (e.g. milestones are not

reached), SPHN may amend or revoke the approved award and:

    a.   if the grant has not yet been transferred, it may amend or withhold it;

    b.   if the grant has already been transferred, it may demand partial or full repayment of the grant.

2. Prior to taking such measures, SPHN will hear the parties concerned and communicate the amendment or revocation in the form of a ruling.

Chapter 6   Grant continuation, reporting and monitoring

6.1 Activity report

1. SPHN grantees must submit an annual activity report to the MO no later than 3 months after the end of the calendar year.
2. The following information must be included in the project activity report:

    a.   summary;

    b.   main achievements and results;

    c.   next steps.

6.2 Financial report

1. Annual financial reports are also to be submitted and must disclose the following:

    a.   Use of SPHN funds;

    b.   Own contributions "in cash" and "in kind" by the involved partners.

2. Financial reports are compiled by the grant administration office of the host institution. They must be reviewed, signed and sent to the MO in a timely manner.
3. Financial reports must be submitted no later than 3 months after the end of the calendar year.

6.3 Funding continuation

1. The activity and financial reports will be reviewed by the EB and the NSB.
2. Based on the progress made, the EB will submit a recommendation to the NSB.
3. The final decision on releasing the next payment is taken by the NSB and communicated by the MO.

Chapter 7   Closing Provisions

These funding regulations were adopted by the NSB on 9 March 2017 and approved by the SERI together with the "Zusatzprotokoll zur Leistungsvereinbarung 2017-2020 zwischen der Schweiz. Eidgenossenschaft und der SAMW".

Table of abbreviations

DEG	Data Expert Group
EB	Executive Board
ELSI	Ethical-Legal-Social-Issues
ELSIag	Ethical-Legal-Social-Issues advisory group
FOPH	Federal Office for Public Health
IAB	International Advisory Board
IT	Information Technology
MO	Management Office
NSB	National Steering Board
PH	Personalised Health
SAMS	Swiss Academy of Medical Sciences
SBP	Swiss Biobanking Platform
SERI	State Secretariat for Education, Research and Innovation
SIB	Swiss Institute of Bioinformatics
SNSF	Swiss National Science Foundation

Glossary

Anonymous data	Data which cannot (without disproportionate effort) be traced to a specific person.
Clinical data management system	A clinical data repository which contains both patient structured and unstructured data.
Driver projects	These vertical projects are based in a concrete research field (e.g. cancer research/oncology) and will push the development of clinical data management systems in all University Hospitals by testing data interoperability & data sharing principles within the whole network. Milestones are infrastructure based.
Encoded data	Data linked to a specific person via a code.
Horizontal initiatives (projects)	Projects that are "devoted to build a progressive shareable interoperable data system" and the dynamic, transparent and shared consent management as well as the core support of technical platforms.
Infrastructure	Resources, personnel, and softwares that are necessary for the installation of the required network. Computers are considered as consumable.
Infrastructure development projects	Projects that thrive to develop and test new technologies, methods and infrastructures for personalized health related research in connection with horizontal initiatives.
Vertical initiatives (projects)	Projects (e.g. "driver" projects, infrastructure development projects) developing and testing new technologies, methods and infrastructures for personalized health related research which will drive horizontal initiatives.