Swiss Personalized Health Network:

Funding Regulations

(01.03.2017; first revision 06.06.2018; second revision 10.05.2021, third revision 22.09.2022)

approved by the State Secretariat for Education, Research and Innovation on 07.10.2022.

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

– the Dispatch ERI 2017-2020 (BFI-Botschaft 2017-2020)

– the Dispatch ERI 2021-2024 (BFI-Botschaft 2021-2024)

– the Final Report "Vorbereitung Implementierung Aufbauorganisation SPHN-Initiative" (15.12.2016)

– the Rules of Procedure of the Swiss Personalized Health Network (27.02.2018, revised on 10.05.2021)

– the White Paper "Funding Principles of the Swiss Personalized Health Network" (01.03.2017, revised on 10.05.2021)

– 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 2021-2024 zwischen der Schweizerischen Eidgenossenschaft und der Schweizerischen Akademie der Medizinischen Wissenschaften SAMW im Rahmen der 'Swiss Personalized Health Network (SPHN)' Initiative" (12.05.21).

issues the following Regulations:

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 was given to the development of a nationally coordinated data infrastructure ensuring data interoperability of local and regional information systems.

In the second **period 2021-2024**, funding priority is given to implementation and sustainability by investing in data interoperability, data standardization, research infrastructure, and the successful networking of data providers, data producers and research institutions within the Swiss research and healthcare landscape. The

A project of

SAMW **ASSM**
Schweizerische Akademie der Medizinischen Wissenschaften
Académie Suisse des Sciences Médicales
Accademia Svizzera delle Scienze Mediche
Swiss Academy of Medical Sciences

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creation of lighthouse research platforms and related output will, in collaboration with the ETH Domain initiative PHRT, 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, hardware, 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 progressive shareable data ecosystem of SPHN is being built following a nationwide project matrix including:

– **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;

– **Vertical initiatives (projects)** that include the development and testing of infrastructures (including new technologies, methods) and their validation and implementation through research-based projects (including "Driver" projects, "Demonstrator" projects, "National Data Streams") for personalized health.

The task list of shareable data infrastructures to be implemented and/or developed include clinical research data warehouses, federated data catalogues/platforms, semantic interoperability and data quality, data security, data transfer and data sharing platforms, bioinformatics and data analytics, interoperability with biobanking, training facilities, a national Data Coordination Center, and research-based Driver projects, Demonstrator projects, and National Data Streams.

2 Types of funding and funding schemes

2.1 Funding principles (see White Paper "Funding Principles"; the Funding Regulations take precedent over the Funding Principles)

2.1.1 Projects have to demonstrate a clear and practical step forward towards nationwide data interoperability including clinical phenotype data, healthy citizens data, –*omics* data, imaging data, lab data, and other human data.

2.1.2 Projects must convincingly demonstrate adherence to the Ethical Framework for Responsible Data Processing between all SPHN partners as defined by the ELSIag. The ELSIag, together with the SPHN Data Coordination Center (DCC) and SIB's legal department, will elaborate legally and ethically appropriate solutions for data and sample access, exchange, privacy, and trust. Access to data and samples for all SPHN partners shall be possible and granted at no financial profit by partner institutions.

2.1.3 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)[1] to match the funds provided by SPHN.

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[1] a) Competitive infrastructure grants (e.g., cohort studies) are eligible as own contribution provided that they support the goal of SPHN. A commitment letter from the institution shall be provided to confirm that the infrastructure is sustainable and will be used and maintained after the end of the project.
  b) Institutions shall decide alone whether they want to use competitive research grants as own contribution.
  c) Footnote 1a) and Footnote 1b) do not apply to the projects awarded within the Call for proposals 2017 and the Call for proposals 2018.

2.1.4 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, "Demonstrator" projects, and "National Data Streams").

2.1.5 Ethical, legal and societal implications (ELSI) associated with personalized health research should be addressed within all SPHN funded proposals.

2.1.6 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:

2.2.1 Projects for **infrastructure implementation** (top-down horizontal initiatives; collaboration agreements ["Leistungsvereinbarung"]).

2.2.2 Projects for **infrastructure development** based on work packages (bottom-up horizontal and vertical initiatives; contributions).

2.2.3 **"Driver" projects**, , (vertical initiatives; contributions). Such Driver projects are based in a concrete research field (e.g., cancer research/oncology) or a specific topic (e.g., rare diseases, specific data types) with the purpose to drive the development of appropriate infrastructures and methodologies to ensure nationwide data interoperability within the respective discipline.

2.2.4 **National Data Streams** (vertical initiatives; contributions), are comprehensive projects with a visible research component, assembling a growing set of interoperable clinical, multi-omics, and other data of a given topic and making it accessible for reuse based on an overarching legal and regulatory framework for first-, second-, and third-level research use of data. National Data Streams must have a sustainability concept and a clear governance structure including a defined data sharing and data quality policy.

2.2.5 **Demonstrator projects** (vertical initiatives; contributions), demonstrate the added value of the SPHN data resources and infrastructure elements for data-driven personalized health research, clinical and public health research, and clinical use. Demonstrator projects use the SPHN infrastructures, processes, and frameworks, to demonstrate the utility and fit-for-purpose of those SPHN ecosystem elements and identify gaps.

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

2.3 Funding schemes

SPHN distinguishes between two funding schemes:

2.3.1 **Collaboration agreements** (Leistungsvereinbarungen) for infrastructure implementation projects.

2.3.2 **Competitive calls** for Infrastructure Development projects, Driver projects, National Data Streams, and Demonstrator Projects.

2.4 Collaboration agreements (Leistungsvereinbarungen)

2.4.1 For the implementation of defined and nationally coordinated data infrastructures, SPHN will establish collaboration agreements (Leistungsvereinbarungen) comprising deliverables and a milestone-based payment mechanism.

2.4.2 The NSB approves the scope, timeframe, beneficiaries, and budget of Infrastructure Implementation projects. Proposals are prepared by the SPHN bodies, coordinated by the DCC and Management Office.

2.4.3 Achievement of the defined milestones will be evaluated by the Data Coordination Center (DCC) on, at least, a yearly basis. If SIB is beneficiary of a collaboration agreement, another SPHN body (e.g., HIT-STAG, NAB) will be responsible for the evaluation.

2.4.4 In case of multi-year funding, the next payment will be released only if the planned milestones have been reached to a sufficient degree and the NSB declares acceptance with respect to the work products.

2.5 Competitive calls for proposals

2.5.1 SPHN will organize open and/or targeted calls for project proposals addressing technical, scientific, ethical, and policy challenges to reach the shareable data infrastructure goals aimed for by the initiative; call contents will be based on the task list outlined in Chapter 1 or based on recommendations made by the International Advisory Board (IAB).

2.5.2 The proposals will be evaluated and prioritized by a committee with members of the IAB and additional experts (see Chapter 4).

2.6 Available funding (2017-2024)

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**	**Expenditure limit (Augabenplafond)**
2.	**Horizontal & vertical project types (see section 2.2)**	**46.0 mio**	**Total engagements (Verpflichtungs-kredit)**
a)	Projects for infrastructure implementation[2]		Collaboration agreements (Leistungsvereinbarungen)
b)	Projects for infrastructure development		Contributions
c)	"Driver" projects (vertical initiatives)		Contributions
3.	**BioMedIT**	**18.0 mio**	**Expenditure limit (Augabenplafond)**

[2] In the period 2017-2020, funds allocated to SIB for the DCC were treated under Line 2a; no matching funds rule was applied.

A total budget of CHF 66.9 million is available for the period 2021-2024 (not including provisions from unspent funds from the period 2017-2020):

	Item	CHF	Description
1.	**Management, bodies, symposia, workshops, etc.** **Data Coordination Center**	**5.0 mio** **7.0 mio**	**Expenditure limit (Ausgabenplafond)**
2.	**Horizontal & vertical initiatives (see section 2.2)** - Projects for infrastructure implementation - Projects for infrastructure development - Driver projects - National Data Streams - Demonstrator projects	**36.3 mio**	**Total engagements (Verpflichtungs-kredit)**
3.	**BioMedIT**	**18.6 mio**	**Expenditure limit (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.*

– *The following exceptions have to be considered:*

– *BioMedIT is under the responsibility of SIB. No matching funds rule is applied for BioMedIT, except for delocalized funds.*

3 Requirements for applicants and for submitting an application

3.1 Eligibility criteria for collaboration agreements (Leistungsvereinbarungen)

3.1.1 Beneficiaries should be Swiss higher education institutions (ETH Domain, universities, universities of applied sciences), university hospitals, other public hospitals (e.g., cantonal hospitals), research institutions as defined by SERI[3], or established research consortia (e.g., cohort consortia).

3.1.2 Private sector institutions (e.g., private hospitals, pharma, IT industry) may associate with an SPHN beneficiary for partnering in an Infrastructure Implementation project, but must cover their efforts with their own resources. Conversely, without a formal partnership, SPHN beneficiaries may use SPHN funds to buy products and services from private sector entities according to the deliverables of the respective collaboration agreement.

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[3] According to Art. 15 of the Federal Act on the Promotion of Research and Innovation. For a list of institutions: https://www.sbfi.admin.ch/sbfi/de/home/themen/forschung-und-innovation-in-der-schweiz/foerderinstrumente/forschungseinrichtungen-von-nationaler-bedeutung.html

3.2   Eligibility criteria for competitive calls

3.2.1   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.

3.2.2   Wider participation is also desired, i.e., other universities, research institutions, established research consortia (e.g., cohort consortia), and/or cantonal or private hospitals and industry are encouraged to associate with at least one SPHN partner institution and to submit joint applications.

3.2.3   SPHN funds can only be provided to Swiss higher education institutions (ETH Domain, universities, universities of applied sciences) and university hospitals. Other research institutions, as defined by SERI, established research consortia (e.g., cohort consortia), and/or hospitals (e.g., cantonal hospitals) are eligible for funding as associated applicants. Private sector institutions must cover their efforts with their own resources.

3.3   Setting up a consortium

3.3.1   The main applicant is responsible for setting up a consortium for his or her proposal.

3.3.2   Under certain circumstances (e.g., no Swiss research group can provide the respective know-how), it is possible to include research groups from foreign countries as associated applicants. However, they cannot be funded by SPHN.

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

3.4   Funding duration and conditions

3.4.1   Engagements for approved projects may last for a maximal duration of three years.

3.4.2   Funds can only be allocated until 31 July 2024.

3.4.3   The NSB will decide an overall award budget for each call and for each collaboration agreement (Leistungsvereinbarung).

3.4.4   A letter specifying and confirming own contributions (see Funding Principles, section 5.3) must be attached to the proposal by all institutions requesting funding from SPHN.

3.4.5   No overheads shall be paid for SPHN funded projects.

4 Evaluation procedure for competitive calls

4.1 Proposal pre-screening

4.1.1 The selection of the proposals will be preceded by a formal check by the Management Office.

4.1.2 Proposals that 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 and quickly corrected.

4.1.3 The following formal requirements must be met:

    4.1.3.1 Compliance with the submission deadline

    4.1.3.2 Completeness of the proposal, written in English

    4.1.3.3 Eligibility of the main applicant, co-applicant(s) and associated applicant(s)

    4.1.3.4 Acknowledgement of the need for the provision of own contributions in the case the proposal is approved for funding

    4.1.3.5 Acknowledgement of compliance with the Ethical Framework for Responsible Data Processing and SPHN/BioMedIT Information Security Policy

    4.1.3.6 Compliance with the current Funding Regulations of SPHN.

4.2 Selection criteria

4.2.1 Proposals will be assessed by a subgroup of the relevant SPHN governing bodies, mandated by the NSB and supported by additional ad hoc experts where necessary, for the feasibility of the proposal with regard to the SPHN infrastructure.

4.2.2 Proposals will subsequently be reviewed in one or in two steps by a committee of members of the IAB and additional experts, mandated by the NSB. The committee may invite applicants to present and discuss their proposal.

4.2.3 Proposals will be selected according to the following criteria:

4.2.3.1 Fit within the task list outlined in Chapter 1

4.2.3.2 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

4.2.3.3 Integration of research data and clinical data in a common system

4.2.3.4 Focus to develop the necessary IT and data infrastructures to achieve nationwide common data standards

4.2.3.5 For Driver projects, scientific quality, including added value of the project as a whole;

4.2.3.6 Quality of the data management and data sharing plan

4.2.3.7 Potential for impact on health and clinical decision making

4.2.3.8 Financial planning in general and distribution of the funding (total costs, own contributions, federal grant applications, third party funding)

4.2.3.9 Quality of the project consortium (including governance) and project management plan

4.2.3.10 Quality of the sustainability plan

4.2.3.11 Other evaluation criteria specified in the call document.

4.2.4 The evaluation will be made in due consideration of the personalized-health approach and of the significance for SPHN.

4.2.5 The IAB will submit funding recommendations to the NSB.

4.3 Funding decision

4.3.1 The NSB will decide on approval and rejection of each proposal including funds allocated to approved projects.

4.3.2 If necessary, short-listed main applicants may be invited to present their proposal and discuss it with the NSB.

4.3.3 Upon approval, a ruling or a collaboration agreement will be established between SPHN and successful applicants which will detail the following (see Chapter 5 and 6):

4.3.3.1 Total amount awarded (engagement) and funding duration

4.3.3.2 Payment conditions

4.3.3.3 Reporting obligations.

5 Grants and grant management

5.1 Legal consequences of the award

5.1.1 On the full or partial approval of a grant application (award), the applicants become grantees of SPHN.

5.1.2 Grantees are obliged:

    5.1.2.1 to use the grant in accordance with the conditions set out in the ruling;

    5.1.2.2 to comply with the provisions stipulated in these Funding Regulations and all other rules applicable to the grant.

5.1.3 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.

5.1.4 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

5.3.1 Applicants who withdraw their proposals or are forced to terminate it prematurely must inform the MO in written form stating reasons.

5.3.2 Any unused funds must be reimbursed.

5.4 Amendment and revocation of the award

5.4.1 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, by decision of the NSB, may amend or revoke the approved award and:

    5.4.1.1 If the grant has not yet been transferred, it may amend or withhold it.

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

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

6 Grant continuation, reporting and monitoring

6.1 Activity report

6.1.1 For projects lasting more than twelve months, SPHN grantees must submit an annual activity report to the MO no later than two months after the end of the calendar year. For projects lasting up to twelve months, a final activity report needs to be submitted at the end of the approved running time of the project.

6.1.2 The following information must be included in the project activity report:

6.1.2.1 Summary

6.1.2.2 Main achievements and results

6.1.2.3 Next steps.

6.1.3 For large projects, the NSB may mandate, in addition, a monitoring board composed of SPHN representatives and external experts to periodically 1) review progress on the goals and milestones, 2) identify synergies between different SPHN projects, and 3) propose adjustments to goals, milestones, or other parts of the project plan to ensure efficient use of resources and to prevent redundancies. The monitoring board will report its recommendations to the NSB.

6.2 Financial report

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

6.2.1.1 Use of SPHN funds

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

6.2.2 Financial reports are compiled by the grant administration office of the main applicant's host institution. They must be reviewed, signed and sent to the MO in a timely manner.

6.2.3 Financial reports must be submitted no later than three months after the end of the calendar year.

6.3 Funding continuation

6.3.1 The activity and financial reports will be reviewed by the DCC, ELSIag, monitoring board (if applicable), NSB-A, and the NSB.

6.3.2 Based on the progress made, the DCC, ELSIag, monitoring board (if applicable) and NSB-A will submit a recommendation to the NSB.

The final decision on releasing the next payment is taken by the NSB and communicated by the MO.

7 Closing provisions

These funding regulations were adopted by the NSB on 22 September 2022 and approved by SERI on 07 October 2022. This version replaces the version of 10 May 2021.

Table of abbreviations

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
NSB-A	NSB Ausschuss
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

The SPHN Glossary can be found on the SPHN website: https://sphn.ch/document/sphn-glossary/