Recommendations for organizational structures facilitating adherence to the regulatory framework for data sharing in SPHN-funded projects

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This is a working document, not yet fully consolidated

1. General understanding

The regulatory framework for sharing health-related data for research purposes is given by the law, mainly the Human Research Act, the Federal Act on Data Protection, and cantonal and international laws (e.g., GDPR) where applicable. The use of human biological specimens is not described in this document, but is governed by similar regulations. SPHN only contributes to the organizational structure and processes to facilitate the adherence to the legal framework for the users (e.g., researchers, clinicians) in SPHN-funded multi-stakeholder projects.

In SPHN projects, typically multiple data providers are involved providing patient health data from clinical routine care and research. Data access and data storage may depend on the type of data, the degree of sensitivity of data, the degree of data curation, and the data providers. Data access control and technical data storage do not necessarily have to be under the responsibility of the same stakeholder.

Data access is typically given on a project basis and must be authorized by the data subjects, data providers, and the relevant ethics committee (EC). Data providers are typically hospitals, cohorts, registries for primary health data and universities, ETH domain institutions, analytical platforms or research consortia for research data. If a dataset is to be re-analyzed for quality control or reproducibility of research use (specified in the respective Data Transfer and Use Agreement [DTUA]), access must be granted if ethical and legal requirements are fulfilled (scientific integrity and reproducibility). If a dataset is to be used long-term for further (nested) research projects, a process for data access must be defined by the initial data providers and research consortia and approved by the relevant EC.

Long-term raw data storage is typically the responsibility of the involved data providers and needs to adhere to storage regulations and best practices. Primary health and patient data providers are typically hospitals, cohorts, registries. Research data, including newly generated post-project datasets, are typically stored within universities, ETH domain institutions, hospitals, and analytical platforms. Research data can be stored on BioMed IT/DCC if agreed on by the project partners including data providers.

2. Organizational aspects of SPHN-funded projects

An SPHN National Data Stream (NDS) is a large topic-specific project, approved by the relevant EC, that implicates long-term use of data around long-term research projects with a defined project and data access organization. NDS facilitate project-based collaborations through NDS-specific standardized organizational

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processes according to the Swiss regulatory frameworks and through standardized points-of-contact and procedures.

For driver projects or NDS, roles and responsibilities for data sharing are typically divided into three layers:

1. **Primary data provider level**: responsibility for generating data, granting permission for data access, and consent management.
2. **NDS or driver project level**: responsibility for ethics approval, scientific and organizational coordination, processing and storage of project data, feedback of results and data quality to data providers.
3. **DCC/BioMedIT**: responsibility for proposing data interoperability guidelines for further validation through the collaboration agreements by SPHN and UH, hosting of meta-data catalogue facilitating findability, accessibility, interoperability and reusability of data (FAIR). BioMedIT offers data hosting and processing of research data and technically ensures data accessibility according to the legal framework.

3. Patients' Consent

In the SPHN context, the data provider generally carries the responsibility for the consent management. It is central that changes in consent (e.g., withdrawal) are communicated to the involved SPHN stakeholders of a given project via defined points-of-contact. Each stakeholder concerned shall then take all necessary measures to comply with legal requirements.

To permit the most efficient and ethical use of data, the consent should be as inclusive as possible, following the provisions of the General Consent template of Swissethics:

> *"Data and samples may be used by authorised researchers for research projects within the hospital or in collaboration with public institutions (such as other hospitals) and private entities (such as pharmaceutical companies), in Switzerland and abroad. For research abroad, it must be ensured that at least the same data protection conditions are followed as in Switzerland. The projects may include genetic analyses for research purposes. Research projects relying on your data and samples have to be authorized by the relevant ethics committee."*

4. Data Protection

All participants of any SPHN-funded project must comply with all legal requirements and data protection regulations. The SPHN/BioMedIT Information Security Policy provides respective guidelines. Participants remain fully responsible for implementation and compliance with the legal regulations.

5. Data exchange for research purposes

Contractual agreements for data exchange by data providers (e.g., university hospitals) with SPHN-funded projects shall contain provisions for the long-term use by the project participants and third parties of routinely and project-specific collected data and project-related datasets. The long-term use of data must be authorized by the relevant EC, in compliance with the informed consent of the patient (data subject) and,

if applicable, in compliance with a governance and procedures that have been approved by the relevant EC and empowered by all stakeholders (including data providers).

The governance and procedures are foreseen as follows:

a) Data exchange in SPHN is subject to a project-specific agreement. The DTUA templates from SPHN shall be used for data exchange with SPHN-funded projects. Roles and responsibilities for different data types are summarized in table 1. The following use cases are foreseen in SPHN-funded projects:

- **Long-term, large-scale research projects, EC-approved,** for which a set of data is being exchanged between a data provider (e.g., university hospital) and a defined research consortium. A DTUA specifying the institutions and responsible persons who will provide and access the data, the dataset to be exchanged (Appendix 1 of the DTUA template from SPHN), and the allowed (long-term) use as described in the EC-approved research plan / study protocol (Appendix 2 of the DTUA template from SPHN) need to be submitted to the data provider's single point of contact and signed by all involved parties. In the course of the research project, the consortium will curate and annotate the data from the data provider and integrate it with data from other sources (e.g., omics data), thereby generating an enriched dataset.
- **Nested research projects, EC-approved,** that emerge from and build on the enriched dataset and are *in the scope* of the long-term large-scale research project. The long-term possibility for conducting nested projects and the processes for implementing such nested projects, including the regulatory aspects, must be described in the EC-approved research project and agreed upon with the data providers. Data providers shall be contacted before the start of a nested research project to verify the consent status of data subjects. Amendments to agreements and research plans must be approved by all parties and fulfil the legal and ethical requirements.
- **New projects** that are *not in the scope* of an ongoing long-term research project require a new agreement between all parties involved (including data providers, research consortium that enriched the dataset, third parties) and the approval of the relevant EC.

b) Each data provider shall designate a **single point of contact** for all data requests (for transfer of, access to, or nested project of previously transferred, data from data provider) and must have in place an efficient and transparent process for approving or denying such requests. Requests for exchange of data or for amending existing agreements for exchange of data shall be submitted in a structured manner (according to the SPHN DTUA templates) and formally answered by UH within **30 working days** (ideally including signing of DTUAs and MTAs). If a request is denied, the reasons for rejecting the request shall be provided in writing.

c) SPHN-funded projects shall designate a **single point of contact** for all communication with data providers (including university hospitals) and shall have in place an efficient and transparent process for handling, e.g. revoked consent or clinically actionable findings. Feedback on results and data quality shall be given to data providers in a timely manner.

d) Data providers remain responsible towards data subjects and must track what data has been shared with whom and for what purpose. Responsibilities and liability must be clearly defined in the DTUA. Data providers are responsible for archiving the original data according to legal and ethical requirements and best practices.

e) SPHN-funded projects may not transfer processed or unprocessed data from data providers to any third party without the explicit written agreement of the data providers. If a transfer of data is authorized by a data provider (e.g., university hospital), provisions must be in place guaranteeing accurate and timely consent management and communication of clinically actionable findings.

Table 1: Roles and responsibilities in SPHN-funded projects (example of National Data Streams [NDS])

Data access and storage depends on type of data. Driver project and NDS may follow the proposed organizational structure

Data types	Data provider	Primary storage	Consent management	Permission of data use (check legal & ethics)
Clinical routine data (generated for healthcare)	UH (also cantonal hospitals, or e.g., SAKK)	UH (also cantonal hospitals, or e.g., SAKK)	UH (also cantonal hospitals, or e.g., SAKK)	UH (also cantonal hospitals, or e.g., SAKK)
Clinical research data **(incl. registries, cohorts)** (generated for research, coded or anonymized data)	University, ETH, University of applied sciences, SAKK, Consortia, Researchers/PI	Universities, ETH, Universities of applied sciences, Hospitals, SAKK BioMedIT/DCC (hosting service)	Primary data/sample providers Researchers/PI	Primary data providers (e.g., UH, SAKK) **+** Driver project or NDS consortia
Non-clinical data (anonymized data)	NDS, driver project, University, ETH, University of applied sciences, Consortia, Researchers/PI	BioMedIT/DCC or universities, ETH, Universities of applied sciences	Primary data providers	Primary data provider (e.g., UH, SAKK) **+** Driver project or NDS consortia