

SPHN Glossary

Version 2, 07 October 2024

TERM	SPHN DEFINITION	SOURCE
Access Right	Permission for a subject to access a particular object for a specific type of operation.	<u>ISO/IEC 20944-1:2013</u>
Anonymization	Irreversible masking or deletion of all items which, when combined, would enable the data subject to be identified without disproportionate effort. In particular, the name, address, date of birth and unique identification numbers must be masked or deleted.	<u>HRO Art. 25</u>
Audit	Independent review and examination of records and activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures.	<u>NIST SP 800-32</u>
Authentication	The verification of the identity of a user, process, or device, often as a prerequisite to allowing access to resources in an information system.	<u>NIST SP 800-128</u>
Authorization	The procedure to verify whether an entity is eligible to access a requested network or service.	<u>NIST SP 800-120</u>

Backup system	The entire system that supports the process of restoring copies of data, so that these copies may be used to recover the original after data loss. Organizing the storage space and media required and managing the backup process can be complex, and corporate backup systems normally include a central module that supports this management, identifying the data to be recovered and the method to be used, logging activities and their outcome, managing media etc. This central system interacts with 'backup clients' installed on each machine that is backed up, which respond to the instructions of the central system and which generate the file copies, produce local logs etc.	<u>SCTO Glossary, version 2.0</u>
BioMedIT Node	An information technology infrastructure provider, consisting of a high-performance compute and storage infrastructure, skilled data scientists and support personnel.	SPHN
Coding	De-identifying data or biological material in a way that from the perspective of a person who has no access to the key linking the data to a specific person, the data or biological material is to be characterized as anonymized. May also be referred to as pseudonymization. The key must be stored separately from the biological material or personal data by a person to be designated in the application who is not involved in the research project.	<u>HRO Art. 26</u>
Confidentiality	Property that information is not made available or disclosed to unauthorized individuals, entities, or processes.	<u>ISO/IEC 27000</u>
Control	The measure that is modifying risk.	<u>ISO/IEC 27000</u>
Controller	The person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.	<u>FADP Art- 5, let. j</u>
Data	Data means any information subject to processing in the performance of the Research Project (or Project) or subsequent reuse. <i>The definitions of the different Data has been listed for easier reference at the end of the Glossary.</i>	SPHN

Data Curation	Refers to the transformation of data aimed at ensuring its quality, accessibility, and usability for users, facilitating data integration or analysis. Data Curation can include the following processes: -Selection -Structuring -Annotating with metadata - Mapping to controlled vocabulary (Semantic mapping) -Validation -Cleaning and quality improvements -Verification	SPHN
Data Processing	Any handling of personal data, irrespective of the means and procedures used, in particular the collection, storage, keeping, use, modification, disclosure, archiving, deletion or destruction of data.	<u>FADP Art. 5, let. d</u>
Data Subject	Natural person whose data is processed.	<u>FADP, Art. 5, let. b</u>
Data Transfer and Use Agreement	A legally binding agreement that governs the transfer of data between two parties, when the recipient intends to use them for research purpose. It defines the rights and obligations of the provider and recipient with respect to the use of the data and other related issues, such as confidentiality or intellectual property rights.	SPHN
De-identified Data	Coded (pseudonymized) or anonymized data	SPHN
Disclosure	Transmitting personal data or making such data accessible	<u>FADP, Art. 5, let.e</u>
Encryption	Process of encoding a message or information in such a way that only authorized parties can access it and those who are not authorized cannot.	SPHN

Ethics Committee	<p>An independent body whose responsibility is to assess, within the framework of its responsibilities under Chapter 8 of the HRA, whether research projects and the conduct thereof comply with the ethical, legal and scientific requirements of the HRA. In particular, it shall assess whether the protection of the persons concerned is guaranteed. It may advise researchers in particular on ethical questions and, if so requested by the researchers, comment on research projects not subject to the HRA, and specifically projects carried out abroad.</p>	<p><u>HRA, Art. 51 et seq.</u></p>
Further Use	<p>Any handling, for research purposes, of biological material already sampled or data already collected, and in particular:</p> <ol style="list-style-type: none"> a. procuring, bringing together or collecting biological material or health-related personal data; b. registration or cataloguing of biological material or health-related personal data; c. storage or inclusion in biobanks or databases; d. making accessible or available or transferring biological material or health-related personal data. 	<p><u>HRO Art. 24</u></p>
General Consent	<p>Informed consent of a research participant to unspecified further research uses of a data subject's health-related personal data or human biological material. (In the international academic literature, the closest term to general consent is broad consent).</p>	<p><u>SPHN ELSIag, Ethical Framework, Version 2</u></p>
High-Risk Profiling	<p>Profiling that poses a high risk to the data subject's personality or fundamental rights by matching data that allow an assessment to be made of essential aspects of the personality of a natural person.</p>	<p><u>FADP Art. 5, let. g</u></p>
Human Biological Material	<p>Organs, cells, tissues, body fluids, and components of such material (including DNA and RNA) that have been extracted from a human being. (Other terms employed are: specimen, which is defined as a specific quantity of biological material (e.g. tissue, blood, urine) taken from a single subject or participant at a specific time, and sample, which is defined as a single unit containing material derived from one specimen, e.g. plasma, serum, DNA, cells, etc.).</p>	<p><u>SPHN ELSIag, Ethical Framework, Version 2</u></p>
Information Asset	<p>Knowledge or data that has value to the individual or organization.</p>	<p><u>ISO/IEC 27032</u></p>

Information Security	The protection of information and information systems from unauthorized access or use, disclosure, disruption, modification, or destruction in order to provide confidentiality, integrity, and availability.	<u>NIST SP 800-128</u>
Information Security Event	An occurrence indicating a possible breach of information security or failure of controls.	<u>ISO/IEC 27035-1:2016</u>
Information Security Incident	Single or a series of unwanted or unexpected information security events that have a significant probability of compromising business operations and threatening information security.	<u>ISO/IEC 27000</u>
Integrity	Guarding against improper information modification or destruction, by ensuring information non-repudiation and authenticity.	<u>NIST SP 800-39</u>
Investigator	A person responsible for the conduct of a clinical trial and for the protection of the participants at the trial site; an investigator who takes responsibility for organizing a clinical trial in Switzerland is also a sponsor.	<u>ClinO Art. 2 let. e</u>
IT Infrastructure	Combined set of IT assets for developing, maintaining, and using IT services.	<u>ISO/IEC 19770</u>
Material Transfer Agreement	A legally binding agreement that governs the transfer of biological material and data between two parties, when the recipient intends to use them for research purpose. It defines the rights and obligations of the provider and recipient with respect to the use of the material and data and other related issues, such as confidentiality or intellectual property rights.	<u>SBP Glossary Version 1.2 of October 4, 2018</u>
Monitoring	The act of determining the status of a system, a process or an activity.	<u>ISO/IEC 27000</u>
Participating institutions	Institutions that are active in SPHN projects, including but not limited to institutions that receive funding from SPHN (e.g. private entities or foreign research groups).	<u>SPHN ELSIag, Ethical Framework, Version 2</u>
Personal Data Breach	A breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data.	<u>FADP Art- 5, let. h</u>

Processing	Any handling of personal data, irrespective of the means and procedures used, in particular the collection, storage, keeping, use, modification, disclosure, archiving, deletion or destruction of data.	<u>FADP Art. 5, let. d</u>
Processor	A person, public authority, agency or other body that processes personal data on behalf of the controller.	<u>FADP Art. 5, let. k</u>
Profiling / Personality Profile	Any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyze or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behavior, location or movements.	<u>FADP Art. 5, let. f</u>
Project invention	Any invention resulting from a specific research project, which could be protected according to applicable patent laws.	SPHN
Project Leader	<p>The person responsible for the conduct of the research project in Switzerland and for protection of the participants at the research site.</p> <p>The person also responsible for organizing the research project, and in particular for the initiation, management and financing of the project in Switzerland, provided that no other person or institution headquartered or represented in Switzerland takes responsibility for this (sponsor).</p> <p>The project leader responsible for a research project must:</p> <ol style="list-style-type: none"> be entitled to practice independently the profession specifically qualifying him or her to conduct the research project in question; have the training and experience required to conduct the research project in question; be conversant with the legal requirements for research projects or be able to ensure compliance by calling in appropriate expertise. 	<u>HRO, Art. 3 and 4</u>
Provider	The entity or person providing data.	SPHN
Pseudonymization	<i>See definition of Coding above.</i>	

Re-identification	Any process by which coded personal data or human biological material is matched with the identity of the person from which they were originally sourced.	<u>SPHN ELSIag, Ethical Framework, Version 2</u>
Recipient	The entity or person, to which the data are provided.	SPHN
Research Biobank	Any collection of human biological material and related data, made available for the conduct of research studies.	<u>SPHN ELSIag, Ethical Framework, Version 2</u>
Research Participants	Individuals who contribute data and/or human biological material to research, including both individuals currently or previously enrolled in research projects and patients whose data or human biological material are used in research.	<u>SPHN ELSIag, Ethical Framework, Version 2</u>
Researcher	A natural person doing scientific work with the aim to discover new knowledge.	SPHN
Reuse of Data	Making use of previously collected/deposited data for the purpose of producing derived data or other results	SPHN
Right to Informational Self-Determination	The right to protection against misuse of personal data.	<u>Federal Constitution Art. 13 II.</u>
Security Controls	Management, operational, and technical controls (i.e. safeguards or countermeasures) prescribed for an information system to protect the confidentiality, integrity, and availability of the system and its information.	<u>ISO/IEC TR 19791</u>
Service Provider / Third Party	Any person or entity not related to any scientific project or group/consortium providing a service or submitting a data sharing request.	SPHN
Significant Changes (Amendments)	Significant changes to an authorized research project must be authorized by the ethics committee before being implemented. Exempt from this requirement are measures which have to be taken immediately in order to protect the participants. The project leader shall submit to the ethics committee any application documents specified in Annex 2 which are affected by the change. At the same time, the project leader shall provide information on the reasons for the change. The following are considered to be significant changes:	<u>HRO, Art. 18</u>

	<ul style="list-style-type: none"> a. changes affecting the participants' safety and health, or their rights and obligations; b. in the case of a Category B research project, changes to the protocol which concern the goal or the central topic of the research project; b. a change of research site or conducting the research project at an additional site; or c. a change of project leader or sponsor. 	
Specific Consent	Informed consent of a research participant to a defined/specific research use of his or her health-related personal data or human biological material.	<u>SPHN ELSIag, Ethical Framework, Version 2</u>
Sponsor	A person or institution responsible for the conduct of the research project in Switzerland and for protection of the participants at the research site. The sponsor (and project leader) also responsible for organizing the research project, and in particular for the initiation, management and financing of the project in Switzerland, provided that no other person or institution headquartered or represented in Switzerland takes responsibility for this.	<u>HRO, Art 3</u>
Third Party	A natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data.	<u>GDPR, Art. 4 POINT 10</u>
Withdrawal	Withdrawal of previously given consent (It may also be referred to as Revocation). (Consequences of withdrawal are defined in consent form and should be disclosed with the concerned participant during the consent process).	<u>SBP Glossary Version 1.2 of October 4, 2018</u>

Definition of Data Types

TERM	SPHN DEFINITION	SOURCE
Analyzed Data	New data stemming from analysis performed on Data (could contain also Personal Data)	SPHN
Anonymized Data and Biological Material	Data and human biological material which cannot (without disproportionate effort) be traced to a specific person	HRA Art. 3, let. i
Biometric Data	Personal data resulting from specific technical processing relating to the physical, physiological or behavioral characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data.	GDPR, ART. 4, POINT 14
Coded Data and Human Biological Material	Personal data and human biological material linked to a specific person via a code. May also be referred to as pseudonymized Data.	HRA, Art 3, let. h
Combined Data	Data resulting i.e. of merging or linkage of data originating from different sources.	SPHN
Curated Data	Data that underwent data curation and is ready for data analysis or training of algorithms or other outputs	SPHN
Deposited Data	Data that is stored in a repository for the purpose of reuse (or replication) by other data users.	SPHN
Genetic Data	Information on hereditary properties or properties acquired during the embryonic phase obtained by genetic testing of an identified or identifiable natural person	HRA; Art. 3, let. g
Health-Related Personal Data	Information concerning the health or disease of a specific or identifiable person, including Genetic Data.	SPHN ELSIag, Ethical Framework, Version 2
Personal Data	Any information relating to an identified or identifiable natural person.	FADP, Art. 5, let. a

Primary Data	Direct output of data collection which has not undergone other processing.	SPHN
Sensitive Personal Data	<p>Data on:</p> <ol style="list-style-type: none"> 1. religious, ideological, political or trade union-related views or activities, 2. health, the private sphere or affiliation to a race or ethnicity 3. genetic data 4. biometric data that uniquely identifies a natural person, 5. administrative or criminal proceedings or sanctions. 6. social assistance measures 	<u>FADP, Art. 5, let. c</u>