



Ethical Framework for Responsible Data Processing in Personalized Health Research

Developed by the Swiss Personalised Health Network and endorsed by the Swiss Biobanking Platform and the ETH Domain Strategic Focus Area on Personalised Health and Related Technologies

ELSI Advisory Group – Version 2 (07.05.2018)

I. Scope and Purpose

The Ethical, Legal and Social Implications advisory group (ELSIag) of the Swiss Personalized Health Network (SPHN) was mandated to produce ethical guidance in relation to personal data processing within the SPHN, with particular emphasis on guidance for data sharing. To this aim, the ELSIag has produced an ethical framework (henceforth, the Framework) for the responsible processing of personal data in the SPHN (henceforth, the Network). This framework was then endorsed by the Swiss Biobanking Platform (SBP) and the ETH Domain Strategic Focus Area on Personalised Health and Related Technologies (PHRT). The methodology that led to this Framework included a systematic analysis of international guidelines and it is described in a separate document (available at: <https://www.sphn.ch/en/about/publications.html>). The Framework provides ethical guidance to the partners of the Network as to the collection, storage, analysis and sharing of personal data for research purposes. Health-related personal data are often derived from human biological material. Both data and human biological material are addressed in this new version of the Framework.

Compliance with Swiss laws and with this Framework are requirements for participation in the SPHN funding schemes and activities. The Swiss Biobanking Platform is elaborating tools, guidelines and technical standards for the processing and proper use of human biological material. Participating institutions are advised to refer to such standards for quality-related and other technical issues concerning the processing and appropriate handling of human biological material.

The purpose of the Framework is to ensure that scientific activities in relation to personal data and human biological material conducted in the context of the SPHN meet adequate standards of ethical responsibility, promote the rights, interests and well-being of research participants, ensure the efficient production of valuable scientific knowledge, and generate public trust around the activities of the Network.

The Framework refers to all data types and human biological material that can be usefully employed in the context of health research. This includes health-related personal data and human biological material that were not originally collected for research purposes, as well as data that are not conventionally associated with the practice of medical research (such as geolocalization data, social media content, data from commercial portable sensors, and the like).

The Framework is built on four general principles: respect for persons, privacy, data fairness and accountability. Each principle is followed by a set of specific guidelines intended to assist participating institutions to abide by the principles.

In addition, this document contains a glossary of terms employed in the Framework. While this framework is developed for the purposes of SPHN, its principles and guidelines can be adopted by other programs and institutions.

Disclaimer:

- *The ELSlag and SPHN are not responsible for oversight and compliance with this Framework.*
- *This document will be periodically reviewed and will be amended in consultation with other governing bodies of the SPHN. It will also be supplemented with additional policies according to the needs of the SPHN Network.*
- *Institutions or programs which adopt or endorse this framework and wish to be explicitly named here, should contact directly the SPHN Management Office.*

II. Glossary

The terms below are used in the Framework and they are designed to meet the needs of the SPHN activities.

Additional relevant terms that have not been defined here can be found in the SPHN Glossary (e.g. *pseudonymised*, *encryption*, etc.) available at <https://www.sphn.ch/en/about/publications.html>

Anonymized data and human biological material = data and human biological material that cannot possibly be linked back to an identifiable individual without disproportionate effort.

Coded data and human biological material = personal data and human biological material linked to a specific person via a code.

Data processing = any operation dealing with personal data, irrespective of the means and the procedure employed, and in particular the collection, storage, use, sharing, revision, disclosure, archiving or destruction of such data.

Data subject = natural person whose data is processed.

Further research use = all research activities employing personal data and/or human biological material beyond the scope of initial collection (e.g. health-related personal data collected in the context of one research project and still usable for other studies unrelated to the original one; or clinical data or human biological material initially collected for diagnostic purposes and then analysed for research purposes).

General consent = informed consent of a research participant to unspecified further research uses of his or her health-related personal data or human biological material. (In the international academic literature, the closest term to *general consent* is *broad consent*).

Genetic data = haplotype, genotype and sequence data regarding the genome of an individual, including both genes and non-genic regions of the genome. For the purposes of this Framework, genetic data is also contained in derivatives of DNA, namely RNA and protein sequence data.

Health-related personal data = information concerning the health or disease of a specific or identifiable person, including genetic data.

Human biological material = 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.).

Participating institutions = institutions that are active in SPHN projects, including but not limited to institutions that receive funding from the SPHN (e.g. private entities or foreign research groups).

Personal data = all information relating to an identified or identifiable person, including health-related personal data.

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.

Research biobank = any collection of human biological material and related data, made available for the conduct of research studies.

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.

Right to informational self-determination = the right to exercise control over the use of one's personal information (including health-related personal data and information derived from human biological material).

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.

III. Ethical Principles and Guidelines for Responsible Data Processing in the SPHN

Four ethical principles should guide the conduct of researchers and the activities of institutions that participate in the SPHN when processing personal data or handling human biological material. In particular, this document aims to provide ethical guidance for the sharing of such data and material within the SPHN.

1. Respect for Persons

The rights and dignity of individuals, families, and communities contributing personal data and/or human biological material in the context of research and clinical care, as well as any other type of data that can be useful for biomedical research must be respected, protected, and promoted.

Individuals have universal human rights, enjoy intrinsic moral worth and have a fundamental entitlement to act as autonomous persons. This includes a right to informational self-determination, that is, the right to exercise control over the use of one's personal information (including health-related personal data and information derived from human biological material). These fundamental rights shall always take precedence over the interests of scientific knowledge and shall be respected and protected by anyone who processes personal data or handles human biological material, for any purpose and at any time. Ethics review committees are tasked with safeguarding such rights.

Enrollment in a research study and collection and use of personal data shall be informed and fully voluntary acts. Withdrawal from a research study and, unless technically impossible, removal of personal data from a research database shall never lead to negative consequences for research participants. The appropriate type of consent plays an instrumental role in ensuring the above.

Individuals, families, and communities who agree to participate in a research study and provide health-related personal data and/or human biological material for research purposes, may sometimes do so without direct benefit expectations and mostly due to altruistic motivations or inspired by moral ideals of solidarity. Nevertheless, they have the right to receive at least clinically actionable information that may result from the analysis of their personal data and/or human biological material. The realization of this right is often determined through the applicable consent process.

Guidelines

- a) All personally identifying genetic data shall be made available for further research use by participating institutions if research participants have provided prior informed consent for the specific use in question.
- b) All coded genetic data shall be made available for further research use by participating institutions, provided at least general consent has been obtained.
 - i. A general consent template is being developed by the SAMS and swissethics. Updates on this link: <https://www.samw.ch/de/Ethik/Forschungsethik/Vorlage-GK.html> / <https://www.samw.ch/fr/Ethique/Ethique-de-la-recherche/Modele-CG.html>
- c) Identifiable personal data shall be made available for further research use by participating institutions, provided specific consent has been obtained.
- d) All anonymized genetic data and human biological material shall be made available for further research use by participating institutions provided research participants have been informed about both the purpose and consequences of anonymization and the intention to use such anonymized data for research, and have not explicitly disagreed.
- e) In special circumstances, personal data and human biological material for which neither general nor specific informed consent is available or possible to seek or, when applicable, for which information on the right to dissent has not been provided, can be made available for further research use by participating institutions provided an authorization is obtained by the competent cantonal ethics committee – following the conditions set forth by the law.
- f) Research participants have the right to request for and be provided with information about their health-related personal data and human biological material, including information related to their collection, storage, use and sharing. They should also have the option to request corrections of errors.
- g) Participating institutions should have mechanisms in place that ensure revocations of consent are swiftly acted upon across the Network. Upon revocation of consent, personal data and biological material should no longer be made available for research. Personal data should be removed and human biological material should be destroyed if, upon revocation of consent, the research participant has expressed this preference. However,

complete elimination of all human biological material and data may not be possible. Research participants should be informed – during the consent procedures – of this possibility.

- h) Human biological material and personal data that have already been employed by the time consent is revoked should no longer be used, except if they have been anonymized.
If data are in use at the time of revocation, the ongoing project should be completed provided the participant was informed about this possibility at the consent process.
- i) Clinically actionable findings should be communicated to research participants through competent healthcare professionals, as stipulated at the consent.
- j) Criteria for determining clinically actionable findings will be elaborated by the ELSIag at a later stage and shall guide decisions about re-contacting research participants.
- k) Participating institutions should have standardized procedures regarding the communication of clinically actionable findings and of clinically relevant results in case research participants request disclosure of such results.

2. Privacy

The privacy of research participants and the confidentiality of their personal information must be safeguarded.

All persons possess a fundamental right in not having personal information accessed or distributed without their authorization, or used in inappropriate, illicit, or harmful ways. For this reason, the processing of data such as the collection, storage, use and sharing of personal data and/or human biological material for research purposes shall only take place under the condition that individuals' right to privacy is respected. Individuals have the right to determine what information about themselves is kept confidential and what can be disclosed. This right can be overridden only in exceptional circumstances, such as a public health emergency, national security reasons or urgent medical needs and only according to applicable law.

Appropriate measures for the protection of privacy must be taken, for instance, by implementing security controls, advanced anonymization and cryptography, and by preventing access beyond the authorized research needs. In the context of scientific research, privacy fosters trust in the activity of researchers and institutions that collect, store, use, distribute, access or otherwise process personal data and human biological material, related to both patients and healthy individuals.

To protect privacy, constant compliance with security standards for the storage of data and human biological material is crucial.

All necessary technical and organisational measures should be adopted and continuously reviewed and updated to protect personal data and human biological material from unauthorized access, intentional or unintentional alteration, damage, loss and misuse.

Guidelines

- a) The institutions participating in the SPHN shall abide by data security standards as prescribed by the Data Coordination Centre.
- b) Participating institutions should abide by professional standards of confidentiality with respect to health-related personal data and human biological material as stated in relevant professional codes of conduct.
- c) Participating institutions are responsible for coding and anonymization of personal data and human biological material, as well as for re-identification procedures (e.g. in case of return of clinically actionable findings). Relevant mechanisms are being articulated by the Data Coordination Centre.
- d) The personnel employed in personal data or human biological material related activities shall be appropriately trained on the technical, legal and ethical requirements with regard to data protection.

3. Data Fairness

Data that can be used for research purposes and research results should be made available for further research use to advance the common good of scientific knowledge.

The availability of data is a major determinant of scientific progress. Data can greatly contribute to the advancement of biomedicine and to the improvement of healthcare. The possibility of using data collected and generated in the context of both research and clinical care, as well as other types of data that can be useful for biomedical research is in the interest of the scientific community, individuals and society. This data often has value well beyond its primary purpose of collection and use, provided researchers are able to access it for further analysis. Data and results should thus be shared for further research or clinical use.

Moreover, certain types of data – like reference genetic sequences, for example – are indispensable assets for progress in specific scientific domains and should thus be considered as community resources and be promptly made publicly accessible.

The researchers and institutions originally involved in the creation of a given dataset shall be given full recognition for their work. Researchers and institutions that generated data through public funding shall not have exclusive access rights to these data sources.

Guidelines

- a) The SPHN is committed to maximizing data availability for research use. Therefore, it requires participating institutions to make their relevant data accessible to the Network partners for further research use.
- b) Access to data should be made possible in a timely manner. In case of delayed data releases, a justification should be provided to the SPHN Management Office.
- c) Within the SPHN, partners should make data accessible without financial profit, and cannot grant exclusive data access rights to any other party.
- d) Costs associated with making data or human biological material accessible can give rise to compensation either in kind or through an appropriate data access fee. Such costs should be included in the requested funding.
- e) Data users should give proper recognition and credit to those who provided the data.
 - i. Norms for authorship attribution are specified in the Swiss Academies of Arts and Sciences' recommendations for authorship in scientific publications¹, and should be followed.
 - ii. Issues of intellectual property attribution will be dealt with at the institutional level by each participating institution.
- f) Data shared within the SPHN infrastructure shall be accompanied by a description of the procedures used to generate it, as well as adequate metadata. Moreover, shared data should adhere to formats and standards defined by the interoperability working group led by the Data Coordination Centre to ensure optimal interoperability.
- g) Participating institutions should plan in advance how to disseminate research results to the wider public.

¹ Scientific Integrity Committee of the Swiss Academies of Arts and Sciences, Hess, Ch. W., Brückner, Ch., Kaiser, T., Mauron, A., Wahli, W., Wenzel, U. J., Salathé, M. (2015), Authorship in scientific publications: analysis and recommendations, *Swiss Medical Weekly* 145: w14108. DOI: [10.4414/smw.2015.14108](https://doi.org/10.4414/smw.2015.14108).

4. Accountability

Accountability mechanisms should ensure fair, lawful and transparent processing of personal data and handling of human biological material.

The existence of adequate governance structures is a prerequisite for the use of health-related personal data and human biological material in the context of scientific research.

Accountability requires that participating institutions processing health-related personal data and/or handling human biological material for research purposes can be held responsible for the consequences their activities may have on both research participants and society as a whole.

Compliance with existing legal norms and regulations regarding the use of health-related personal data and human biological material for research purposes is the baseline of accountability. However, whenever appropriate, additional measures should be adopted in order to provide better protection to the legitimate interests of research participants. Prospective research participants should receive information including the purpose of databases and research biobanks to which they contribute data and human biological material, about their for-profit/not-for-profit status, and the conditions under which they will grant other researchers access. Governance procedures and mechanisms adopted by participating institutions should be open to scrutiny. In particular, research participants have a right to access information regarding how an institution processes their data and handles their human biological material, including the conditions under which it grants other users access to such resources.

These basic principles of transparency are constitutive elements of accountability.

Robust accountability mechanisms promote public trust and foster a climate of mutual respect and reciprocity between research institutions, research participants and the general public.

Guidelines

- a) The governance structure of the participating institution must be transparent and auditable.
- b) Participating institutions should clearly designate individuals responsible for the processing of personal data and the management of human biological material.
- c) Quality standards for the handling of human biological material should be clear, transparent and auditable.
- d) Procedures for authorizing access to data and/or human biological material by other participating institutions should be lean, standardized and transparent.
- e) Sharing of coded and non-coded biological material must be regulated and documented in a verifiable manner.
- f) If human biological material is only available in limited quantity, clear policies for prioritizing access requests should be in place. Such policies may include clauses for the return of unused human biological material.
- g) Participating institutions should make sure that employees involved in SPHN activities are made aware of the provisions of this Framework and of the institutional accountability mechanisms.
- h) Requests by third parties for access to data or human biological material produced through SPHN-funding should undergo data access review.
- i) Appropriate functions such as monitoring, performance evaluation and periodic auditing of data security measures shall be undertaken. Results from these activities shall be transmitted to the SPHN Data Coordination Centre. Assessment of the institutional capacities for the management of human biological material shall be conducted by an independent organization such as Swiss Biobanking Platform. Results shall be made available to the SPHN Management bodies upon request.
- j) The participating institutions are responsible for legal compliance with Swiss law, including and not limited to the Federal Act on Research involving Human Beings (HRA), the Federal Act on Data Protection (FADP), and the Federal Act on Human Genetic Testing (HGTA).

References

Main Swiss Legal References and Guidelines/Opinions

- Federal Act on Data Protection (FADP) of 19 June 1992, CC 235.1
- Federal Act on Human Genetic Testing (HGTA) of 8 October 2004, CC 810.12
- Federal Act on Research involving Human Beings (Human Research Act, HRA) of 30 September 2011, CC 810.30
- Ordinance to the Federal Act on Data Protection (DPO) of 14 June 1993, CC 235.11
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) of 20 September 2013, CC 810.301
- Swiss National Advisory Commission on Biomedical Ethics - Biobanks for research - Opinion no. 24/2015 Bern, December 2015
- Swiss Biobanking Platform – Best Practices. General Consent for Research

Main International Declarations

- WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks - Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016
- OECD Recommendations on Health Data Governance of 17 January 2017