Ethical Framework for Responsible Data Processing in the Swiss Personalized Health Network

ELSI Advisory Group (12.06.2017)

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I. Scope and purpose

The Ethical Legal and Social Implications advisory group (ELSIag) of the 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). The methodology that led to this Framework is described in a separate document. 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. It is based on a systematic analysis of international guidelines in this area, which provide comprehensive coverage of additional issues, but it is focussed on the specific needs of the SPHN in its early phase of development. Compliance with national laws and with this framework are requirements for participation in the SPHN funding schemes and activities.

The purpose of the Framework is to ensure that the scientific activities in relation to personal data that are conducted in the context of the SPHN meet adequate standards of ethical sustainability, 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 that can be usefully employed in the context of health research. This includes data that were not originally collected for research purposes (such as clinical data), 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 SPHN partners to abide by the principles.

In addition, this document contains definitions of the most relevant terms employed in the Framework and a checklist that corresponds to the guidelines.

Disclaimer:

- The ELSIag 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.

II. Definitions

Further research use = all research uses beyond the scope of initial collection (e.g. data collected in the context of one research project and still usable for other studies unrelated to the original one; clinical data initially collected for diagnostic purposes).

Participating institution = institutions that are active in SPHN but do not necessarily receive funding (i.e. private entities or foreign research groups).

Research participants = individuals who contribute data to SPHN research, including, both individuals currently or previously enrolled in a research study and patients whose data are used in a SPHN-related study; and more generally the natural and legal persons whose data are being processed.

Personal data = all information relating to an identified or identifiable person.

Secondary findings = all medically-relevant information that can be derived from data analyses beyond the initial scope of collection.

Encoded = data linked to a specific person via a code.

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

General consent = informed consent of a research participant to unspecified further research uses of her personal data. It is synonymous to *broad consent*.

Data processing = any operation 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 data.

Informational self-determination = the right to control one's own personal information, i.e. the right to determine which information will be disclosed when, to whom and for what purpose.

III. Ethical principles and guidelines for responsible data processing in the Swiss Personalized Health Network (SPHN)

We have identified four ethical principles that should guide the conduct of researchers and the activities of institutions that participate in the SPHN when processing health related personal data. In particular, this documents aims to guide the sharing of such data within the SPHN.

1. Respect for persons

The rights and dignity of individuals, families and communities contributing health data in the context of research and clinical care, as well as other types 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 control the terms under which personal data are processed. 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 for any purpose and at any time.

Enrollment in a research study and collection and use of personal data shall always 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.

Individuals, families, and communities who agree to participate in a scientific study and provide personal data for research purposes, do so without an expectation of direct benefit and mostly out of 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 data.

Guidelines

a) Non-genetic health-related data, whether they are encoded or not, shall be made available for further research use by participating institutions, provided at least general consent has been obtained.

b) All anonymized genetic data shall be made available for further research use by participating institutions provided research participants have agreed to anonymization, have been informed about the intention to use such anonymized data for research and have not dissented to it.

c) All encoded 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 available in Annex 1 and is recommended for use.

d) All personally identifying genetic data shall be made available for further research use by participating institutions if individuals have provided prior informed consent for the specific use in question.

e) Health related personal data for which informed consent is not available, nor possible to obtain 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 (HRA art. 34).

f) Participating institutions should have mechanisms in place that ensure revocation of consent is swiftly acted upon across the network of data users.

g) Clinically actionable findings should be communicated to research participants through caregivers, unless participants have objected to being recontacted during informed consent procedures.

h) Criteria for determining clinically actionable findings will be elaborated by the ELSIag at a later stage and shall guide decisions about recontacting research participants.

i) 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

Privacy and confidentiality must be safeguarded.

All persons possess a fundamental interest in not having personal information accessed or distributed without their authorization, or used in inappropriate illicit, or harmful ways. For this reason, the collection, use and sharing of personal data for research purposes shall only take place under the condition that individuals' right to privacy is respected.

Appropriate measures for the protection of privacy and against the risk of privacy breaches must be taken, for instance, by implementing security controls such as techniques of data de-identification, advanced data anonymization and cryptography, and by preventing access to personal data beyond the specific research needs. In the context of scientific research, confidentiality fosters trust in the activity of researchers and institutions that collect, store, use, distribute or access personal data, both patients' data as well as data of healthy individuals.

All necessary data security measures should be adopted to protect personal data form unauthorized access, intentional or unintentional alteration, damage, loss and misuse.

Guidelines

a) The institutions participating in the SPHN shall abide by data security measures as prescribed by the Data Coordination Center.

b) Participating institutions should abide by professional standards of confidentiality with respect to personal data as stated in relevant professional codes of conduct.

c) Participating institutions are responsible for encoding and anonymization of personal data, as well as for reidentification procedures (e.g. in case of return of clinically actionable findings). Relevant mechanisms will be articulated by the Data Coordination Center.

d) The personnel employed in data-related activities shall be appropriately trained on the technical, legal and ethical requirements with regard to data protection and the management of personal data.

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. These data often have value well beyond their primary purpose of collection and use, provided other researchers are able to access them for further analysis. Data and results should thus be shared among researchers or anyway be made available 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 should be made available as soon as possible.

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 though 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 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 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 publications[1], and should be followed.

ii. Issues of intellectual property attribution will be dealt with at the institutional level by each SPHN partner.

f) Data shared within the SPHN infrastructure shall be accompanied by a description of the procedures used to generate them, 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 Center to ensure optimal interoperability.

g) SPHN partners 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, Christian W. Hess, Christian Brückner, Tony Kaiser, Alex Mauron, Walter Wahli, Uwe Justus Wenzel, Michelle Salathé, *Swiss Medical Weekly* 145: w14108. doi: 10.4414/smw.2015.14108.

4. Accountability

Accountability mechanism should ensure fair, lawful and transparent data processing.

The existence of adequate governance structures is a prerequisite for the use of personal data in the context of scientific research.

Accountability requires that organizations processing personal data for research purposes can be held responsible for the consequences their activities may have on both research participants and society as a whole. This requirement fulfils basic duties of fairness.

Compliance with existing legal norms and regulations regarding the use of personal data 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.

Procedures and mechanisms adopted by research organizations to govern their data processing activities should be open to scrutiny. In particular, research participants have a right to access information regarding how an organization processes their data including the conditions under which it grants access to other data users. 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) Given the implications that the use of personal data may have for research participants, responsibilities for the use of such data should be clearly identifiable.

b) The governance structure of the participating institution must be transparent and auditable.

c) Procedures for authorization of data access requests within the participating institutions should be lean, standardized and transparent.

d) Requests by third parties for access to data produced through SPHN-funding should undergo ethical assessment.

e) Appropriate functions such as monitoring, performance evaluation and periodic auditing of data security measures shall be undertaken by each participating institution. Results from these activities should periodically be transmitted to the SPHN Data Coordination Center.

f) The participating institutions are responsible for legal compliance with human research and data protection laws.