



SPHN: FRAMEWORK FOR RESPONSIBLE DATA PROCESSING

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Ethical, Legal, Societal Implications

Mandate:

- ◆ Identify key ELSI challenges
- ◆ Invite other SPHN bodies to submit ELSI concerns
- ◆ Provide advise to SPHN (principled recommendations)
- ◆ Submit the recommendations to the NSB for approval

ELSlag

- health law
- data protection law
- bioethics
- sociology of medicine
- health policy
- patient safety
- patient perspectives



Cyrill Berger
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Ethical framework for responsible data processing* in the Swiss Personalized Health Network

**collection, storage, use, sharing, revision, disclosure, archiving and destruction of data, irrespective of the means*

Why an ethical framework?

- ◆ The law sets the bare minimum
- ◆ The law is rooted in ethical principles that are not always self-evident and need to be articulated
- ◆ To ensure all involved partners and stakeholders are aware of the ethical vision of SPHN
- ◆ To offer guidance when there is ambiguity

Methodology

Review of available guidance on data sharing

| | |
|-----------------|---|
| Time span | 1996 - 2017 |
| Organizations | <ul style="list-style-type: none"> • National, international public policy organizations • Scientific societies and professional organizations • Public research funders • Research platforms / consortia • Governmental organizations |
| Types of data | <ul style="list-style-type: none"> • Biomedical research data • Clinical trial data • Electronic health records • Genetic and genomic data • Public health data |
| # documents | 49 |
| # organizations | 32 |

List of organizations

| | |
|--|---|
| International public policy organizations | CIOMS; GA4GH; ICH; OECD; P3G; UNESCO |
| National public policy organizations | ETHIK RAT (DE) Comité d'Éthique du CNRS (FR) Office for Science and Technology Policy (US) NEK-CNE (CH) Nuffield Council on Bioethics (UK) President's Council of Advisors on Science and Technology (US) The Royal Society (UK) Swiss Clinical Trial Organization |
| Scientific societies, professional organizations, research platforms and consortia | WMA; EFPIA; HUGO; ESHG; ICGC; Sanger Institute |
| Research funders | MRC; NSF; NIH; Wellcome Trust; Public Health Research Data Forum Partners; Cancer Research UK; NHMRC; RCUK; H2020 |
| Governmental organizations | Council of Europe, G8 Science Ministers, EU Commission |

What we searched for

- ◆ **Principles** = statements indicating a valuable state of things, a right, interests to be protected or promoted, activities to be encouraged, or risks to be avoided.
- ◆ **Guidelines** = requested or prescribed actions needed to achieve what the principles indicate as valuable.

What we obtained

- ◆ A set of the most frequently recalled principles being relevant for SPHN activities
- ◆ A draft framework composed of relevant principles and suitable guidelines

The Ethical Framework

- ◆ Draft discussed and amended by the ELSIag
- ◆ Extensive feedback from other SPHN bodies and stakeholders
 - Executive Board
 - National Steering Board (NSB)
 - Individuals' comments
- ◆ Framework approved by the NSB



The rights and dignity of individuals, families and communities participating in research must be respected, protected and promoted.

Privacy and confidentiality must be safeguarded.

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.

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

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.

GUIDELINES

- ◆ Consent
- ◆ Use of general (broad consent)
- ◆ Clinically actionable findings should be communicated
- ◆ Mechanisms in case of revocation of consent
- ◆ Return of results if requested

PRIVACY

Privacy and confidentiality must be safeguarded.

GUIDELINES

- ◆ Following pre-defined standards of data security, confidentiality, encoding and anonymization.
- ◆ Raising privacy awareness in data operators.

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.

GUIDELINES

- ◆ Timely access.
- ◆ No profit but cost claims possible.
- ◆ No exclusivity rights agreements.

ACCOUNTABILITY

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

GUIDELINES

- ◆ Transparent governance structures.
- ◆ Procedures for authorizing data access requests by other SPHN partners.
- ◆ Ethical assessment of data access requests by third parties.

The Ethical Framework

- Additional guidelines needed
 - Samples
 - Clinical actionability
 - Encoding and anonymization procedures
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- The framework can be amended in the future (live document)
- Possible uses beyond SPHN

