Swiss Personalized Health Network

SAMW ASSM
Schweizerische Akademie der Medizinischen Wissenschaften
Académie Suisse des Sciences Médicales
Academia Svizzera delle Scienze Mediche
Swiss Academy of Medical Sciences

SPHN: FRAMEWORK FOR RESPONSIBLE DATA PROCESSING

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Chair of the ELSIag

ELSI advisory group
Ethical, **L**egal, **S**ocietal **I**ssues

Mandate:

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

ELSI advisory group

Composition

Expertise in:

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

ELSI advisory group

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 provide advise when there is ambiguity

The Swiss legal landscape

- Human Research Act (HRA), 810.30
- Human Research Ordinance (HRO), 810.301:

	Further use of biological material and genetic data (Art. 32 HRA)	Non-genetic health-related personal data (Art. 33 HRA)
Personally identifying	1) Informed consent to specific research projects only. *(Art. 32 Para. 1 HFG, Art. 28 HRO)*	*4) "Informed consent*" to research projects in general *(Art. 33 Para. 1 HRA, Art. 31 HRO)*
Encoded	*2) "Informed consent*" to research projects in general *(Art. 32 Para. 2 HRA, Art. 29 HRO)*	5) Can be used for research purposes in general, if information was given in advance & absence of dissent *(Art. 33 Para. 2 HRA, Art. 32 HRO)*
Anonymized	3) can be used for research purposes in general, if information was given in advance re anonym. & absence of dissent *(Art. 32 Para. 3 HRA, Art. 30 HRO)*	Not in the scope of the HRA *(Art. 2 Par. 2 lit. c HRA)*

The Swiss legal landscape

- Human Research Act (HRA), 810.30
  - 30 September 2011
- Human Research Ordinance (HRO), 810.301:
  - 20 September 2013

- Federal Act on Data Protection (FADP), 235.1
  - 19 June 1992

- Human Genetic Testing Act (HGTA), 810.12
  - 8 October 2004

- Verordnung über das elekronische Patientdossier (EPDV), 816.11
  - 22 March 2017

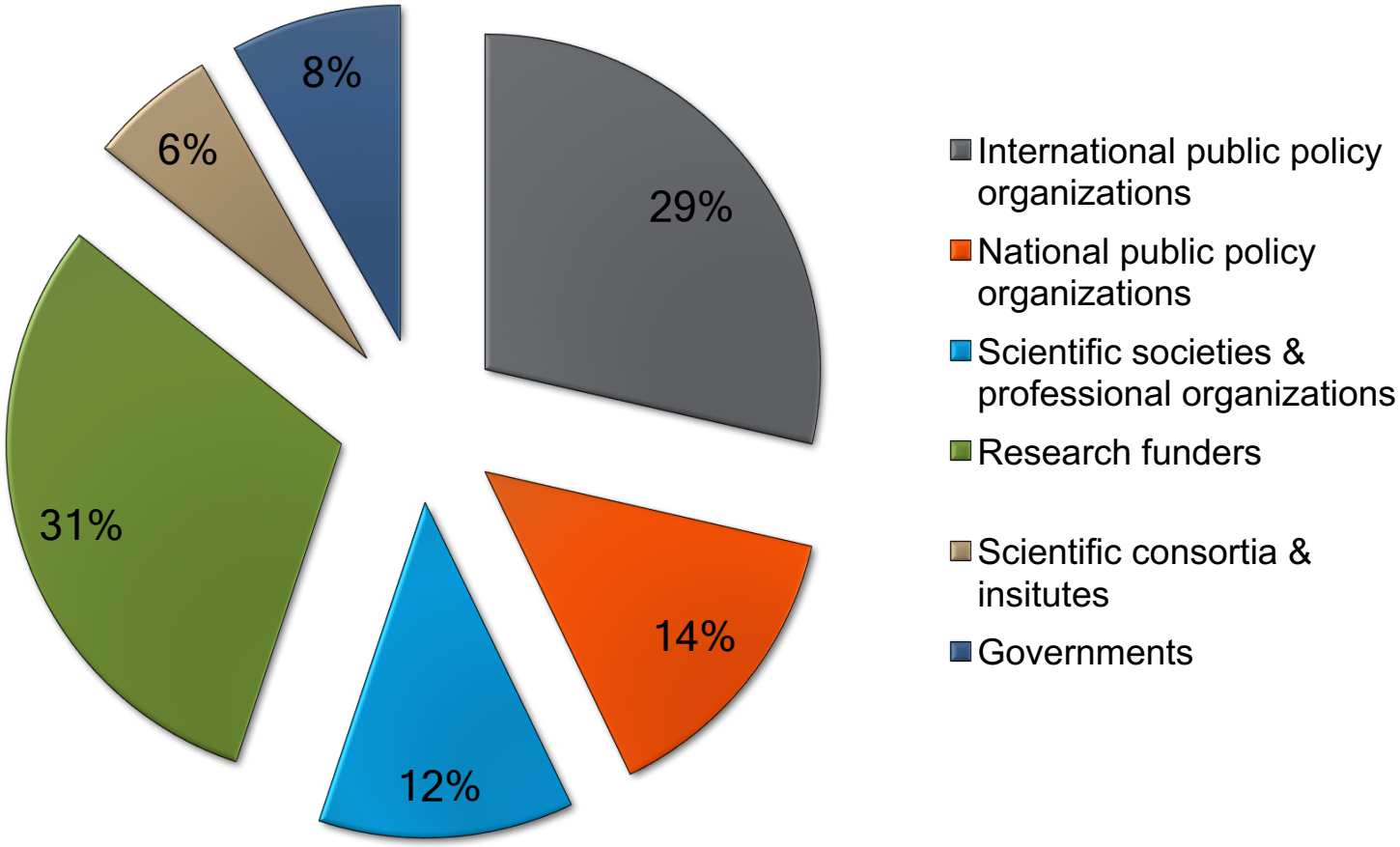
Methodology

Review of available guidance on data sharing	
Time span	1996 - 2017
Organizations	• National, international public policy organizations • Scientific societies and professional organizations • Public research funders • Research platforms / consortia • Governmental organizations
Types of data	• Biomedical research data • Clinical trial data • Electronic health records • Genetic and genomic data • Public health data
# documents	49
# organizations	32

Methodology

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

Guidance documents by category



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 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.

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.

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

Guidelines

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

Guidelines

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

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