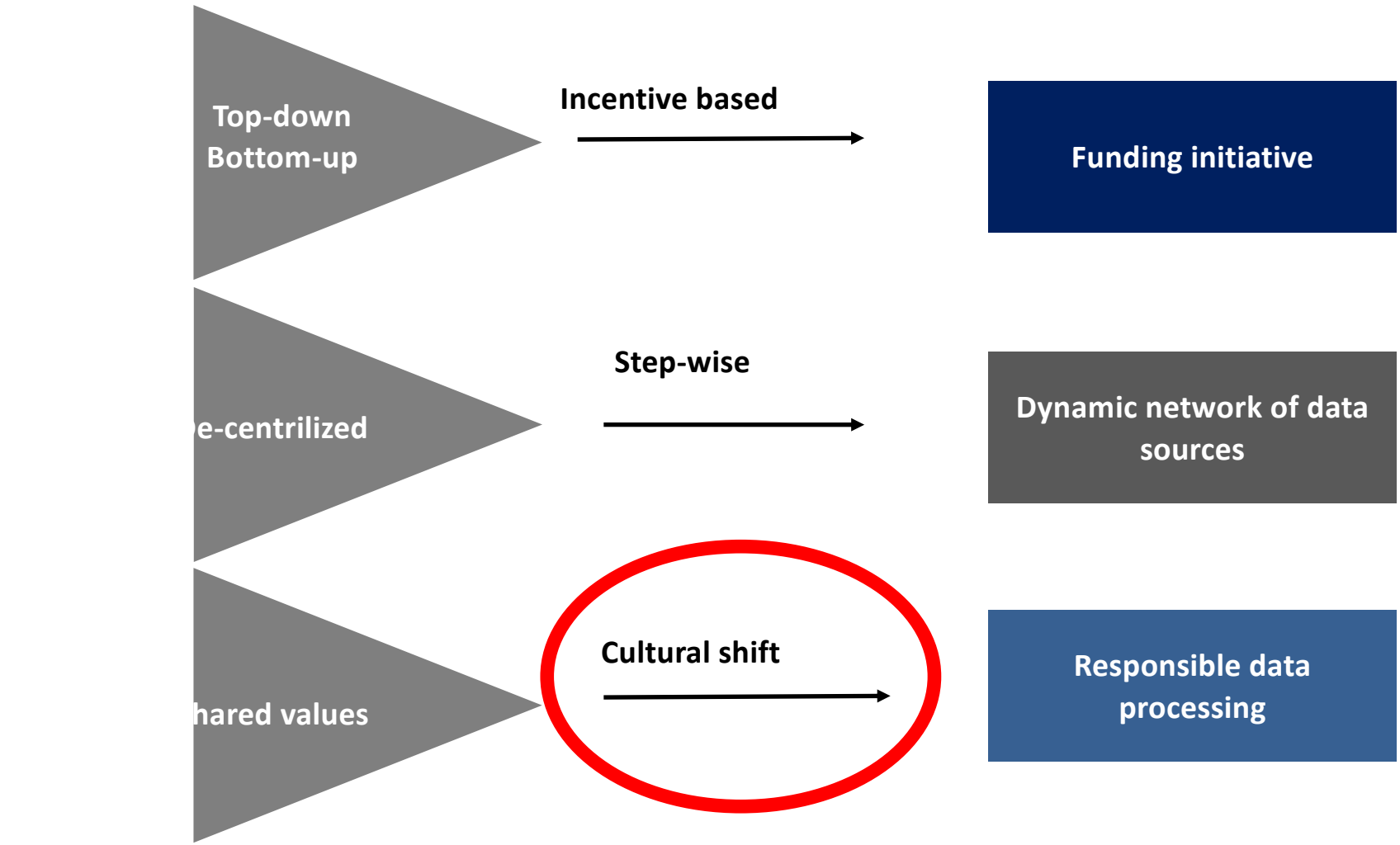
Ethical, Legal and Societal Implications: Contributions of the ELSI advisory group

Effy Vayena
ETH Zurich

Chair of the ELSIag


Top-down
Bottom-up
Incentive based
Funding initiative
e-centrilized
Step-wise
Dynamic network of data sources
hared values
Cultural shift
Responsible data processing

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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

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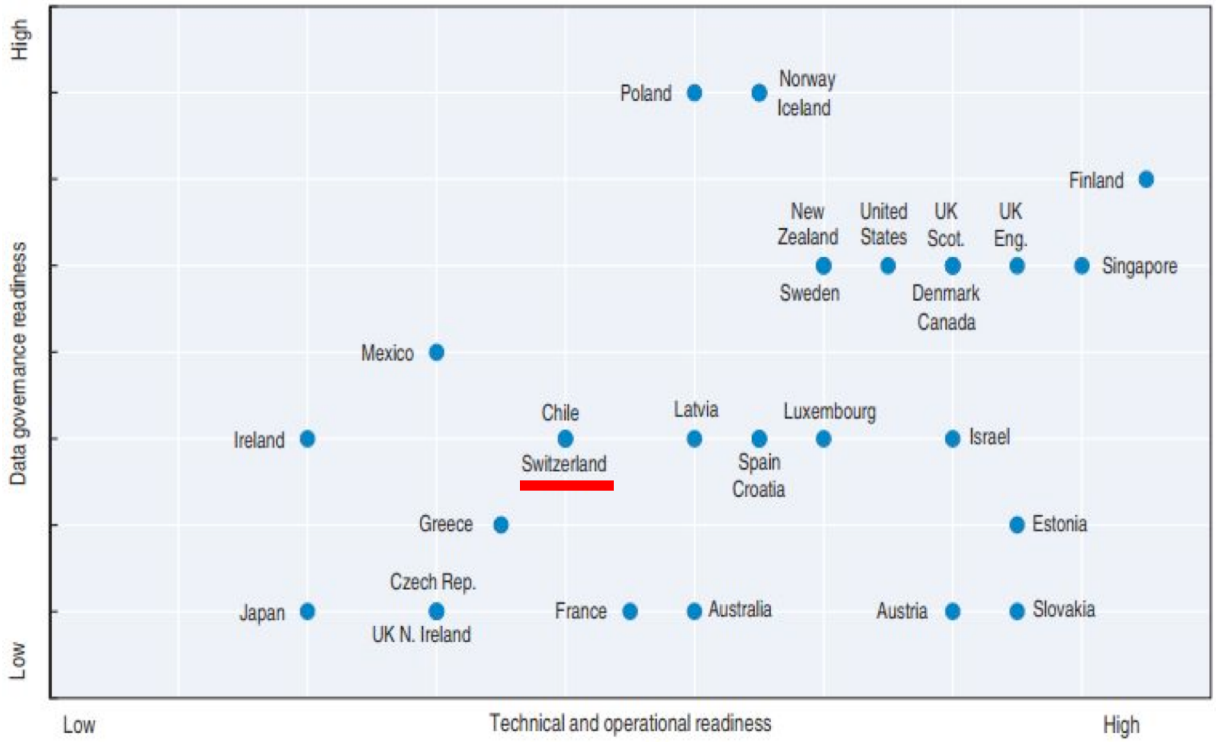
Present of data “readiness”



Source: OECD http://www.oecd.org/health/graph-of-the-month.htm

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Overview

- **Ethical Framework for Responsible Data Processing in Personalized Health Research**
- **Glossary**
- **Data Transfer and Use Agreement template**
- **Return of individual research findings**

1. Why?
2. What?
3. How?

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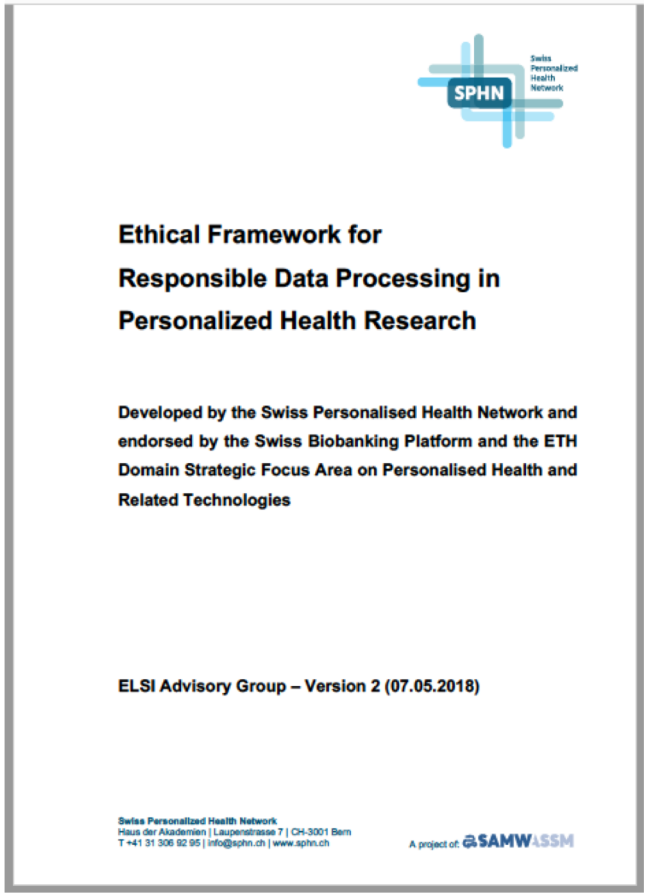
1. Ethical Framework



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)

Swiss Personalized Health Network
Haus der Akademien | Laupenstrasse 7 | CH-3001 Bern
T +41 31 306 92 95 | info@sphn.ch | www.sphn.ch

A project of: SAMW ASSM

Ethical Framework for Responsible Data Processing in Personalized Health Research

- Version 2, dated May 7, 2018, endorsed by:

  Swiss Biobanking Platform (SBP)

  ETH-Domain Strategic Focus Area in Personalized Health and Related Technologies (PHRT)

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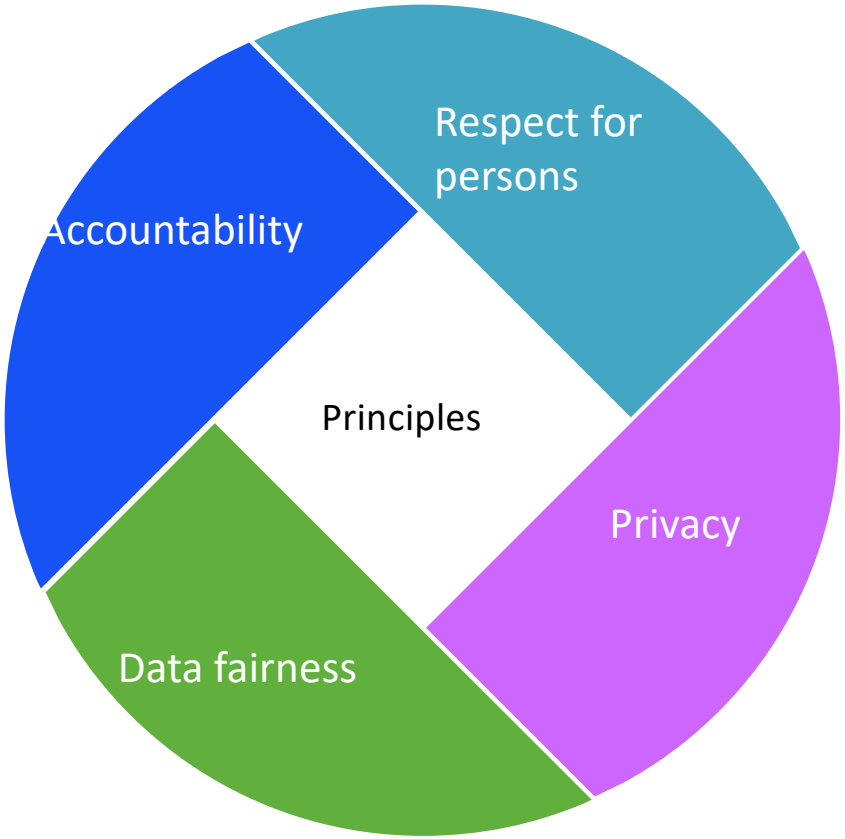
1. Ethical Framework (cont‘d)

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.

1. Ethical Framework (cont‘d)



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.

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1. Ethical Framework (cont'd)

Content: Related Guidelines

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 / General Consent
- Information about how health-related personal data and samples are processed, and corrections of errors
- Mechanisms in place in case of revocation of consent
- Clinically actionable findings to be communicated by healthcare professionals, as stipulated at the consent. Standardized procedures needed.

1. Ethical Framework (cont‘d)

Content: Related Guidelines (cont‘d)

PRIVACY

Privacy and confidentiality must be safeguarded.

GUIDELINES

- Following pre-defined standards of data security and confidentiality.
- Responsible for coding, anonymization and re-identification procedures.
- Raising privacy awareness in data operators.
- Training of employees needed on the technical, legal and ethical requirements with regard to data protection.

1. Ethical Framework (cont‘d)

Content: Related Guidelines (cont‘d)

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

- Maximizing data availability: data to be accessible to the Network partners for further research use.
- Timely access.
- Access without financial profit but cost claims possible.
- No exclusive data access agreements.
- Proper recognition and credit to be give to data provider.

1. Ethical Framework (cont‘d)

Content: Related Guidelines (cont‘d)

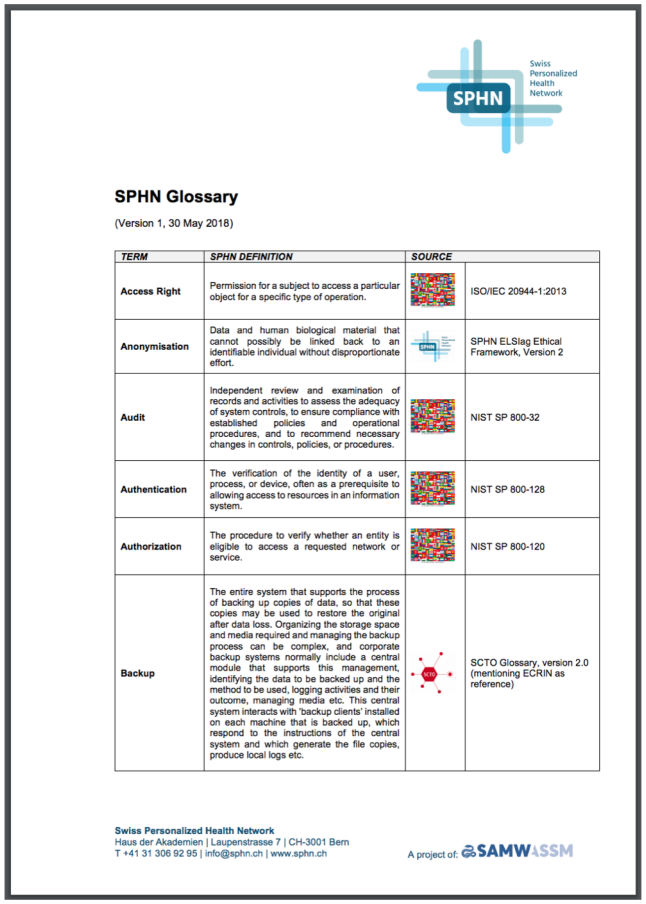
ACCOUNTABILITY

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

GUIDELINES

- Transparent and auditable governance structures.
- Procedures for authorizing access requests by other SPHN partners.
- When scarcity: clear policies for prioritizing access requests should be in place.
- Ethical assessment of access requests by third parties.

2. Glossary



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SPHN Glossary

(Version 1, 30 May 2018)

TERM	SPHN DEFINITION	SOURCE	
Access Right	Permission for a subject to access a particular object for a specific type of operation.		ISO/IEC 20944-1:2013
Anonymisation	Data and human biological material that cannot possibly be linked back to an identifiable individual without disproportionate effort.		SPHN ELSIag Ethical Framework, Version 2
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.		NIST SP 800-32
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.		NIST SP 800-128
Authorization	The procedure to verify whether an entity is eligible to access a requested network or service.		NIST SP 800-120
Backup	The entire system that supports the process of backing up copies of data, so that these copies may be used to restore 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 backed up 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.		SCTO Glossary, version 2.0 (mentioning ECRIN as reference)

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T +41 31 306 92 95 | info@sphn.ch | www.sphn.ch

A project of: SAMW ASSM

SPHN Glossary

- Version 1, dated May 30, 2018

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2. Glossary (cont‘d)

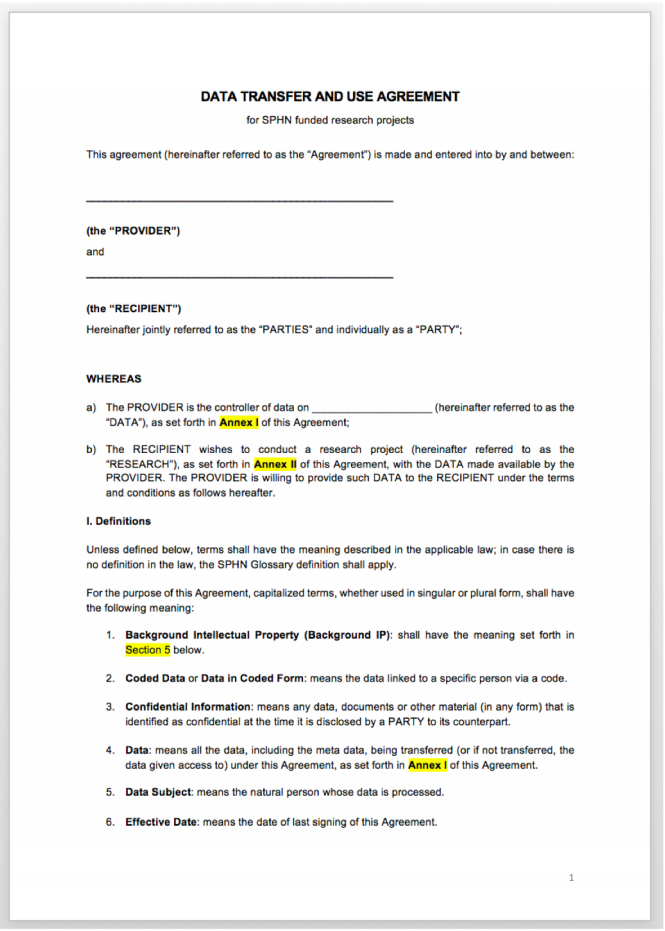
Why a Glossary?

- To make sure SPHN stakeholders, partners and participating institutions are on the same page.

Content?

- Most frequently used legal and technical terms within the SPHN environment.

3. Data Transfer and Use Agreement template



DATA TRANSFER AND USE AGREEMENT

for SPHN funded research projects

This agreement (hereinafter referred to as the "Agreement") is made and entered into by and between:

_____

(the "PROVIDER")

and

_____

(the "RECIPIENT")

Hereinafter jointly referred to as the "PARTIES" and individually as a "PARTY";

WHEREAS

a) The PROVIDER is the controller of data on _____ (hereinafter referred to as the "DATA"), as set forth in **Annex I** of this Agreement;

b) The RECIPIENT wishes to conduct a research project (hereinafter referred to as the "RESEARCH"), as set forth in **Annex II** of this Agreement, with the DATA made available by the PROVIDER. The PROVIDER is willing to provide such DATA to the RECIPIENT under the terms and conditions as follows hereafter.

I. Definitions

Unless defined below, terms shall have the meaning described in the applicable law; in case there is no definition in the law, the SPHN Glossary definition shall apply.

For the purpose of this Agreement, capitalized terms, whether used in singular or plural form, shall have the following meaning:

1. **Background Intellectual Property (Background IP)**: shall have the meaning set forth in Section 5 below.
2. **Coded Data** or **Data in Coded Form**: means the data linked to a specific person via a code.
3. **Confidential Information**: means any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed by a PARTY to its counterpart.
4. **Data**: means all the data, including the meta data, being transferred (or if not transferred, the data given access to) under this Agreement, as set forth in **Annex I** of this Agreement.
5. **Data Subject**: means the natural person whose data is processed.
6. **Effective Date**: means the date of last signing of this Agreement.

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Data Transfer and Use Agreement template

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3. Data Transfer and Use Agreement template (cont'd)

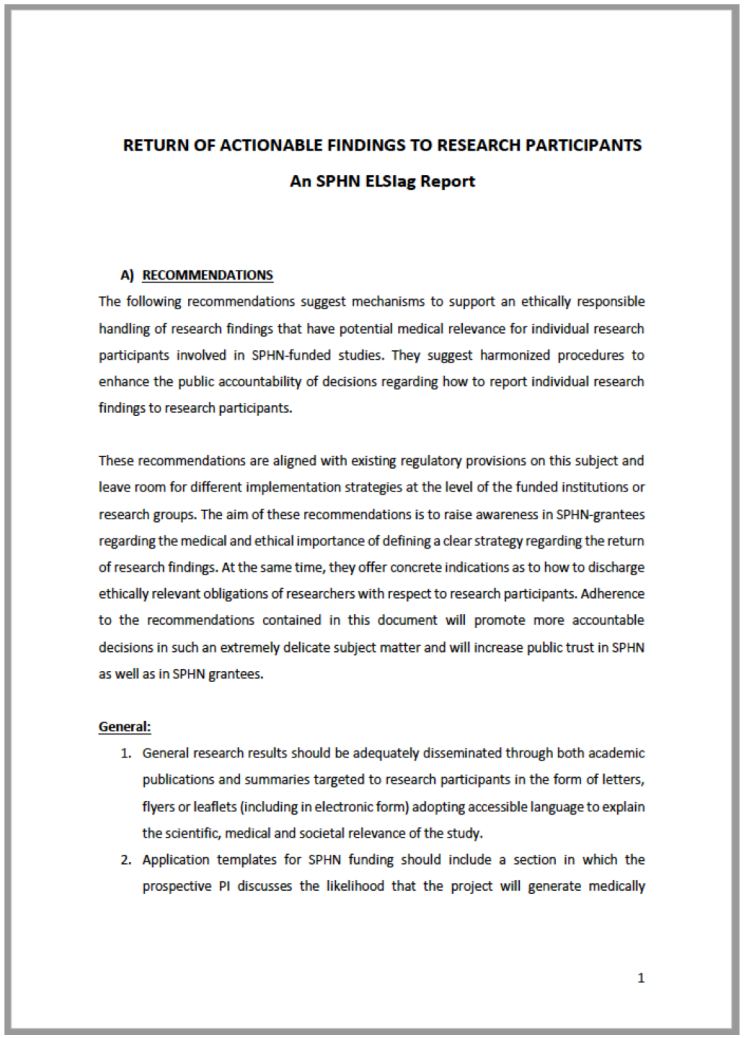
Why such a template?

- To harmonize the way data are transferred by the hospitals to the researchers, or used by the latter;
- To facilitate multicenter research projects.

Goal?

- To provide SPHN stakeholders with a DTUA template ready to use.

4. Return of actionable findings to research participants (cont‘d)



RETURN OF ACTIONABLE FINDINGS TO RESEARCH PARTICIPANTS

An SPHN ELSIag Report

A) RECOMMENDATIONS

The following recommendations suggest mechanisms to support an ethically responsible handling of research findings that have potential medical relevance for individual research participants involved in SPHN-funded studies. They suggest harmonized procedures to enhance the public accountability of decisions regarding how to report individual research findings to research participants.

These recommendations are aligned with existing regulatory provisions on this subject and leave room for different implementation strategies at the level of the funded institutions or research groups. The aim of these recommendations is to raise awareness in SPHN-grantees regarding the medical and ethical importance of defining a clear strategy regarding the return of research findings. At the same time, they offer concrete indications as to how to discharge ethically relevant obligations of researchers with respect to research participants. Adherence to the recommendations contained in this document will promote more accountable decisions in such an extremely delicate subject matter and will increase public trust in SPHN as well as in SPHN grantees.

General:

1. General research results should be adequately disseminated through both academic publications and summaries targeted to research participants in the form of letters, flyers or leaflets (including in electronic form) adopting accessible language to explain the scientific, medical and societal relevance of the study.
2. Application templates for SPHN funding should include a section in which the prospective PI discusses the likelihood that the project will generate medically

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5. How?

- Research and analysis
- Deliberation (within the advisory group)
- Deliberation (with the stakeholders)
- Expert hearings
- Living documents

Cultural shift
Governance

Constructive dialogue

Synergy

Convergence